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JEFF and SHERILYN CAMPIE

UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

UNITED STATES OF AMERICA, ex rel., JEFF and SHERILYN CAMPIE;

STATE OF ARKANSAS, ex rel., JEFF and SHERILYN CAMPIE;

STATE OF CALIFORNIA, ex rel., JEFF and SHERILYN CAMPIE;

DISTRICT OF COLUMBIA, ex rel., JEFF and SHERILYN CAMPIE,

STATE OF DELAWARE, ex rel., JEFF and SHERILYN CAMPIE;

STATE OF FLORIDA, ex rel., JEFF and SHERILYN CAMPIE;

STATE OF GEORGIA, ex rel., JEFF and SHERILYN CAMPIE;

STATE OF HAWAII, ex rel., JEFF and SHERILYN CAMPIE;

STATE OF ILLINOIS, ex rel., JEFF and SHERILYN CAMPIE;

STATE OF INDIANA, ex rel., JEFF and SHERILYN CAMPIE;

Case No. CV 11-941 EMC

SECOND AMENDED COMPLAINT

JURY TRIAL DEMANDED

STATE OF LOUISIANA, ex rel.,
JEFF and SHERILYN CAMPIE;

COMMONWEALTH OF
MASSACHUSETTS, ex rel.,
JEFF and SHERILYN CAMPIE;

STATE OF MICHIGAN, ex rel.,
JEFF and SHERILYN CAMPIE;

STATE OF MONTANA, ex rel.,
JEFF and SHERILYN CAMPIE;

STATE OF NEW YORK, ex rel.,
JEFF and SHERILYN CAMPIE;

STATE OF NEVADA, ex rel.,
JEFF and SHERILYN CAMPIE;

STATE OF NEW HAMPSHIRE, ex rel.,
JEFF and SHERILYN CAMPIE;

STATE OF NEW JERSEY, ex rel.,
JEFF and SHERILYN CAMPIE;

STATE OF NEW MEXICO, ex rel.,
JEFF and SHERILYN CAMPIE;

STATE OF OKLAHOMA, ex rel.,
JEFF and SHERILYN CAMPIE;

STATE OF RHODE ISLAND, ex rel.,
JEFF and SHERILYN CAMPIE;

STATE OF TENNESSEE, ex rel.,
JEFF and SHERILYN CAMPIE;

STATE OF TEXAS, ex rel.,
JEFF and SHERILYN CAMPIE;

COMMONWEALTH OF VIRGINIA, ex
rel., JEFF and SHERILYN CAMPIE;

STATE OF UTAH, ex rel.,
JEFF and SHERILYN CAMPIE;

STATE OF WISCONSIN, ex rel.,
JEFF and SHERILYN CAMPIE;

and,

CITY OF CHICAGO, ex rel.,
JEFF and SHERILYN CAMPIE;

Plaintiffs/Relators,

vs.

GILEAD SCIENCES, INC.,
333 Lakeside Drive
Foster City, CA 94404

Defendant.

INTRODUCTION

1. On behalf of the United States of America ("the Government"); the states of Arkansas, California, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Louisiana, Michigan, Montana, New York, Nevada, New Hampshire, New Jersey, New Mexico, Oklahoma, Rhode Island, Tennessee, Texas, Utah, and Wisconsin; the commonwealths of Massachusetts and Virginia; the City of Chicago; and the District of Columbia (collectively "the States"), Plaintiffs/Relators Jeff and Sherilyn Campie ("Relators") bring this *qui tam* action against Defendant Gilead Sciences, Inc. ("Gilead") under the False Claims Act, 31 U.S.C. § 3729 *et seq.* ("the FCA") and similar false claims statutes enacted by the States.[1]

2. Gilead manufactures and sells extremely expensive drug products, which are largely paid for by the Government and the States through reimbursement programs such as Medicare, Medicaid, the Department of Defense ("DOD") TRICARE program, and the Federal Employee Health Benefits Program ("FEHBP"), and through direct sales to the DOD, the Department of Veterans Affairs ("VA"), the Federal Bureau of Prisons ("BP"), the United States Agency for International Development ("USAID"), the Public Health Service ("PHS"), and other federal and state health benefit and relief agencies and programs (collectively, "the Government Payment Programs").

[1] Relators have in this Second Amended Complaint strived to comply with the Court's directive that their amended complaint be streamlined under the notice pleading standards of Fed. R. Civ. P. 8. *See* Order Granting Defendants' Motion to Dismiss (Doc. 117) ("Dismissal Order"), at 10-11 & 25. Out of an abundance of caution against defense accusations of lack of particularity under Rule 9(b), however, and for purposes of preserving appellate review of the Dismissal Order, Relators hereby reallege and incorporate by reference the factual allegations and the exhibits of the First Amended Complaint.

3. Gilead has caused to be submitted false claims for payment under the Government Payment Programs for Gilead drug products that were not approved by the Government (the "Affected Drug Products"), because they were manufactured using an Active Pharmaceutical Ingredient ("API") that Gilead sourced in huge amounts and on the cheap from an unregistered and uninspected Chinese manufacturer known as Synthetics China, Ltd. ("Synthetics China"). The Government through the Food and Drug Cosmetic Act (the "FDCA") and governing regulations required Gilead to obtain Government approval of a Prior Approval Supplemental ("PAS") supplementing its prior New Drug Application(s) ("NDA") for the Affected Drug Products ***before*** distributing the drug products containing API manufactured at the Synthetics China facility. In knowing disregard of the controlling statutes and regulations, however, Gilead obtained large quantities of API from Synthetics China, which it surreptitiously incorporated into finished drug products introduced into commerce before obtaining the required PAS approval. Because Gilead failed to submit and secure approval from the Government's Food & Drug Administration ("FDA") of a PAS for the Synthetics China facility, there was and could be no effective approval of the Affected Drug Products under the FDCA, and accordingly the corresponding claims for payment failed to satisfy conditions of payment under the Government Payment Programs and were therefore false claims under the FCA.

4. After distributing massive quantities of the Affected Drug Products without submitting any PAS for the Synthetics China plant, Gilead belatedly submitted a PAS in late 2008. However, because the API produced by Synthetics China was contaminated and failed to satisfy the required specifications under the NDAs for the Affected Drug Products, Gilead submitted a fraudulent PAS for the Synthetics China facility through falsified test results, false express certifications and other false statements to the Government. Gilead knew when it submitted its after-the-fact PAS that the API produced at the Synthetics China facility plant was contaminated, was not bioequivalent to the API previously approved by the FDA, and was of substandard strength, quality, purity, potency, safety and/or efficaciousness. Gilead nevertheless fraudulently induced the FDA to approve its PAS in order to falsely claim that it had complied

with conditions of its participation in the Government Payment Programs by securing FDA approval of its adulterated drug products, which, in reality, did not comply with the conditions for such FDA approval.

5. By engaging such conduct as to Synthetics China and other unapproved API suppliers, Gilead caused and obtained payment for the Affected Drug Products in violation of conditions for its participation in the Government Payment Programs, and caused plan sponsors, patients, pharmacists, drug wholesalers and others to submit false claims for payment or reimbursement for the Affected Drug Products in violation of express conditions of payment under the Government Reimbursement Programs.

6. Gilead also knowingly generated false statements, falsified test results, false certifications and other false records to conceal its impermissible use of the contaminated API to manufacture drug products that did not in truth qualify for payment under the Government Payment Programs. Gilead's false records included not only the falsified test results and false certifications submitted in support of its belated PAS, but also falsified Certificates of Analysis ("COAs"), falsified Material Status Notifications ("MSNs") certifying that its drug products conformed to required specifications, and falsified tracking numbers to conceal that the contaminated API had originated with the unapproved Synthetics China facilities.

7. Relators do not allege mere noncompliance with regulations pertaining to the manufacture of a properly approved drug product; rather, as alleged in detail below, Gilead intentionally distributed drug products that were not approved by the Government and not within the scope of an approved NDA effective for such drugs -- intentionally and materially misrepresenting the source, quality and purity of API to give the false appearance of having obtained the Government approval needed to qualify the Affected Drug Products for payment under the Government Payment Programs, causing it and others to file false claims for payment of the unapproved Affected Drug Products under the Government Payment Programs.

8. A false statement, certification or record is material under the FCA if it has "a natural tendency to influence, or be capable of influencing, the payment or receipt of money or

property." 31 U.S.C. § 3729(b)(4); *United States v. Bourseau*, 531 F.3d 1159, 1170-71 (9th Cir. 2008). Relators in this action on behalf of the Government and the States seek to recover payments made for the Affected Drug Products based on the false claim that the Affected Drug Products were approved by the Government or covered by an approved NDA effective for such drugs under the FDCA when they were in fact ineligible under the Government Payment Programs. The Government and the States are not obligated to pay for the Affected Drug Products under such circumstances. Indeed, had the Government known the truth, it could not have permitted Gilead to sell or otherwise distribute the Affected Drug Products in interstate commerce, let alone to obtain payment under the Government Payment Programs.

9. Recovery of the Government and the States payments for the Affected Drug Products is warranted under the FCA and the state false claims acts, therefore, because Gilead: (a) knowingly caused to be presented a false or fraudulent claim for qualification or participation in the Government Payment Programs, and (b) knowingly made, used, or caused to be made or used, a false record or statement material to a false or fraudulent claim presented to the Government and the States under the Government Payment Programs. Plaintiffs specifically assert Gilead's FCA liability under a factually false theory, an express certification theory, an implied certification theory and a promissory fraud theory.

10. This action also seeks redress through federal and state law retaliation claims arising out of the adverse employment actions Gilead took against Relator Jeff Campie while he was engaged in conduct protected under federal and state law, including the FCA.

JURISDICTION AND VENUE

11. This Court has subject matter jurisdiction over this civil action pursuant to 28 U.S.C. §§ 1331 & 1345, and 31 U.S.C. §§ 3730 & 3732. This Court has supplemental and pendant jurisdiction over Relators' claims arising under the laws of the various states pursuant to 28 U.S.C. § 1367.

12. Personal jurisdiction and venue are proper in this district pursuant to 28 U.S.C. §§ 1391(b) & 1395(a), and 31 U.S.C. § 3732(a), as at least some of Gilead's acts occurred in this district and Gilead is found and regularly transacts business in this judicial district.

PARTIES

13. Plaintiff/Relator Jeff Campie is a United States citizen and an individual residing in California. He was employed by Gilead as the Senior Director of Global Quality Assurance in Foster City, California, from July 2006 to July 2009.

14. Plaintiff/Relator Sherilyn Campie is a United States citizen and an individual residing in California. She was employed by Gilead as an Associate Manager for Quality Control in Foster City, California, from March 2007 to February 2014.

15. As a result of their involvement in the processes and events described herein, Relators have direct and independent knowledge of the false statements, certifications and records through which Gilead caused false claims for payment for the Affected Drug Products to be submitted by it and others to the Government and the States under the Government Payment Programs.

16. Defendant Gilead is headquartered at 333 Lakeside Drive in Foster City, California. Gilead is a publically-traded company engaged in the development, manufacture, promotion, sale, and inter- and intra-state distribution of prescription drug products.

17. Gilead Sciences ULC ("Gilead Alberta") is a wholly-owned subsidiary of Gilead headquartered at 1021 Hayter Road, Edmonton in Alberta, Canada, and is controlled by Gilead.

GENERAL ALLEGATIONS

A. GILEAD'S HEAVY RELIANCE ON GOVERNMENT PAYMENTS

18. Gilead is the world's largest producer of anti-HIV drug therapies, and approximately 57% of its prescription drug product sales occur in the United States.

19. The Government and the States pay for the majority of Gilead's drug products sold within the United States through the Government Payment Programs. According to

Gilead's 2014 Form 10-K, at 7, for example, "Half of all patients taking our HIV medicines in the United States … receive them through federal and state programs …."

20. Gilead in its 2009 Form 10-K, at 19, further acknowledged: "Successful commercialization of our products depends, in part, on the availability of governmental and third-party payer reimbursement for the cost of such products and related treatments. Government health administration authorities, private health insurers and other organizations generally provide reimbursement." Gilead has repeated this statement in every Form 10-K filed since. Gilead has also acknowledged its substantial sales attributable to Medicaid and Medicare, noting in its SEC filing for 2009 that "we have benefited from patients transitioning from Medicaid to Medicare Part D since 2006…." *Id.* at 28.

21. Payments by the Government for Gilead's drug products (including the Affected Drug Products) are tracked by the Government, not only for reporting purposes but also for calculation of the rebates which Gilead must pay the Government and the States under certain of the Government Payment Programs. *See, e.g.*, Office of Inspector General for the Department of Health and Human Services ("OIG") Report OEI-02-11-00170 (Aug. 2014), http://oig.hhs.gov/oei/reports/oei-02-11-00170.pdf, Appendix A and B (utilizing 2013 Medicare Part D data relating to Gilead's anti-HIV drugs (including Emtriva, Truvada & Altripla)). For example, the OIG reported that in 2013 alone 52,574 Medicare Part D beneficiaries received 441,399 prescriptions of Gilead's Truvada, 27,514 beneficiaries received 237,458 prescriptions of Gilead's Atripla, and 3,119 beneficiaries received 22,821 prescriptions of Gilead's Emtriva; which, in total, represented in excess of $1.002 billion in payments by the Government.

22. In 2008 and 2009 alone, the following quantities of Gilead drug products were purchased by the Government:

- Atripla: $3.2 billion, representing 2.8 million bottles;
- Truvada: $2.6 billion, representing 3.3 million bottles; and
- Emtriva: $518 million, representing 118,000 bottles.

23. Gilead has recognized that, given the considerable degree of Government and State payment for its drug products, it may be subject to their respective false claims laws. For instance, at page 20 of its 2009 Form 10-K, Gilead acknowledged:

> False claims laws prohibit anyone from knowingly and willingly presenting, or causing to be presented for payment to third party payors (including Medicare and Medicaid), claims for reimbursed drugs or services that are false or fraudulent, claims for items or services not provided as claimed or claims for medically unnecessary items or services. Our sales and marketing activities may be subject to scrutiny under these laws. Violations of fraud and abuse laws may be punishable by criminal and/or civil sanctions, including fines and civil monetary penalties, as well as the possibility of exclusion from federal health care programs (including Medicare and Medicaid). If the government were to allege against or convict us of violating these laws, there could be a material adverse effect on our results of operations.

B. FOR A DRUG PRODUCT AS MADE TO PARTICPATE IN AND RECEIVE PAYMENT UNDER THE GOVERNMENT PAYMENT PROGRAMS, THE GOVERNMENT'S DRUG APPROVAL AND MANUFACTURING REQUIREMENTS MUST BE MET

24. The Government Payment Programs include (a) reimbursement programs ("Government Reimbursement Programs") such as Medicare, Medicaid, TRICARE and the FEHBP, and (b) direct-pay programs ("Government Direct Pay Programs") that govern the purchase of drug products by agencies such as the VA, the BP, USAID and the Public Health Service. Manufacturers such as Gilead are paid under Government Reimbursement Programs upon the submission of claims by plan participants or sponsors, and are paid directly under the Government Direct Pay Programs upon submission of their own claims to the Government.

25. All the payments made by the Government and the States under the Government Payment programs are ultimately drawn on the public fisc of the Government and State.

26. The Government Payment Programs are jointly administered by various arms, departments, agencies or divisions within the same Government or State, and (as in the case of Medicare and Medicaid) often by two divisions within the same department.

27. As alleged more particularly below, the federal Government Payment Programs are governed by an integrated, inter-Governmental protocol under which a given drug product's eligibility for participation and payment is conditioned upon Government approval of that drug

under the FDCA and compliance with Government's requirements set forth in the FDCA and Government's regulations promulgated thereunder by the FDA.

28. Government approval of a new drug product under the FDCA takes two forms: initial and supplemental. 21 U.S.C. §§ 355 & 356a.

29. Drug manufacturers like Gilead must for all new drugs obtain initial Government approval through an NDA; to do so, the manufacturer must submit to the Government detailed information, including certified clinical and other test results, must identify the production facilities that manufacture the drug product and its components (including its API), and must certify that those production facilities will comply with mandatory current Good Manufacturing Practices ("cGMP") required under the FDCA.

30. After an NDA has been approved by the Government, drug manufacturers like Gilead must furthermore obtain Government approval of a PAS in the event of a change in the manufacturing process that has a substantial potential adverse effect on the identity, strength, quality, purity or potency of the previously approved NDA drug. The PAS ensures continuing compliance with the specifications and conditions of the original NDA, and must be approved ***before*** any drug product ***made with the change*** can be released for commercial sale. 21 U.S.C. § 356a(a). In particular, the FDCA provides:

> [A] drug made with a major manufacturing change may be distributed only if, ***before the distribution of the drug so made***, the holder involved submits to the Secretary a supplemental application for such change ***and the Secretary approves the application.***

21 U.S.C. § 356a(c)(1) (emphasis added). *See, e.g.*, *United States v. Marcus*, 82 F.3d 606, 610 (4th Cir. 1996) (upholding criminal liability for manufacturer's undisclosed addition of two inactive pharmaceutical ingredients not included in the FDA-approved NDA, given their unknown effect on the safety and efficacy of the drug product).

31. Changes requiring Government approval under a PAS ("major changes") specifically include changes in the quality, purity and source (i.e., manufacturing facility) of an approved drug product's API. In the case of a change in an API's manufacturing facility, the PAS must be accompanied by the manufacturer's certification, supported by validation test

results, attesting that the new facility is capable of producing API equivalent to the previously approved drug product and that the new facility will comply with the cGMPs.

32. Where a manufacturer intends to produce a previously approved NDA drug at a facility not previously registered with and inspected by the Government, the drug products "so made" at the new facility are not approved by the Government and may not by distributed in interstate commerce unless and until the facility is registered and the Government approves a properly validated PAS.

33. The requirement of PAS approval vitiates the manufacturer's ability to rely on the original NDA approval and compendium listing for those drug products made without approval of the change (such as those manufactured using contaminated API obtained from an unregistered and not previously inspected facility). Consequently, where a drug manufacturer obtains approval of an NDA for a new drug based on test results establishing the quality and purity of drugs manufactured at a specified manufacturing source, that approval is not effective for drugs subsequently manufactured at a different manufacturing facility unless and until a PAS is submitted and approved by the FDA confirming the safety, purity and efficacy of the drugs sourced at the new facility.

34. Drug products manufactured at a new facility and distributed without mandatory PAS approval are deemed to be "adulterated" or "misbranded" under the FCDA. *See, e.g., In re Fosamax (Alendronate Sodium) Prods. Liab. Litig.*, 951 F. Supp. 2d 695, 704 (D.N.J. 2013) (label changes made without PAS approval would cause drug to be misbranded).

35. The foregoing non-discretionary conditions to Government approval of a drug product under the FDCA, alleged in further detail in the following Paragraphs, constitute conditions for participation in and payment under both the Government Reimbursement Programs and the Government Direct Pay Programs.

1. Government Reimbursement Programs

a. Medicare

36. Medicare is a Government health payment program for the elderly, codified as 42 U.S.C. § 1395 *et seq.* Medicare is administered for the Government jointly by the FDA and by

the Center for Medicare and Medicaid Services ("CMS"), both of which are Operating Divisions of the same Governmental agency, the United States Department of Health and Human Services ("HHS").

37. Commencing on January 1, 2006, Medicare Part D provides comprehensive outpatient prescription drug coverage. Payment for a drug product under Medicare Part D is limited, however, to a "covered outpatient drug," defined as one which is "approved for safety and effectiveness as a prescription drug" under the FDCA. 42 U.S.C. § 1395w-102(e); 42 U.S.C § 1396r-8(k)(2).

38. For drug product eligibility for payment under the Medicare program, CMS relies on the FDA safety and effectiveness determinations under the FDCA, which CMS describes as a "condition of approval" to "be eligible for Medicare coverage":

> Because the FDA is charged with regulating whether devices or pharmaceuticals are safe and effective for use by consumers, ***generally we will not accept a request for a*** device or ***pharmaceutical that has not been approved or cleared for marketing by the FDA*** for at least one indication;
>
> ***
>
> ***Whereas the FDA must determine that a product is safe and effective as a condition of approval***, CMS must determine that the product is reasonable and necessary as a condition of coverage under section 1862(a)(1)(A) of the Act. ***CMS adopts FDA determinations of safety and effectiveness***, and CMS evaluates whether or not the product is reasonable and necessary for the Medicare population. Although ***an FDA-regulated product must receive FDA approval or clearance*** (unless exempt from the FDA premarket review process) for at least one indication ***to be eligible for Medicare coverage***, except for Category B devices under an IDE clinical trial (*see* 60 FR 48417, September 19, 1995), FDA approval/clearance alone does not generally entitle that device to coverage.

Medicare Program: Revised Process for Making Medicare National Coverage Determinations. 68 Fed. Reg. 55634, 55636 (Sept. 26, 2003) (emphasis added).[2]

[2] http://www.cms.gov/Medicare/Coverage/DeterminationProcess/Downloads/FR09262003.pdf

39. Government approval of the drug product under the FDCA is thus an essential prerequisite to a pharmaceutical manufacturer's eligibility to participate in and obtain payment for its drug product under the Medicare program

40. Consistent with the foregoing, the CMS Medicare Eligibility Manual furthermore specifically states that eligible drug products must be approved "for marketing," including Government approval of "the manufacturing and processing procedures used by [the pertinent] facilities":

> ***If the FDA has not approved the manufacturing and processing procedures used by [] facilities, the FDA has no assurance that the drugs these companies are producing are safe and effective.*** The safety and effectiveness issues pertain to such factors as chemical stability, purity, strength, bioequivalency, and bioavailability. [¶] Section 1862(a)(1)(A) of the [Social Security] Act requires that drugs must be reasonable and necessary in order to by [sic] covered under Medicare. This means, in the case of drugs, t***he FDA must approve them for marketing***. Section 50.4.1 instructs carriers and intermediaries to deny coverage for drugs that ***have not received final marketing approval by the FDA***, unless instructed otherwise by CMS.

Medicare Benefit Policy Manual, Denial of Medicare Payment for Compounded Drugs Produced in Violation of Federal Food, Drug, and Cosmetic Act. Ch. 15, § 50.4.7 (emphasis added).[3]

41. As indicated above, above and beyond the prerequisite of Government marketing approval under the FDCA for the drug products for which Medicare reimbursement is claimed, CMS retains responsibility to determine that a given drug product or specific drug allotments is furthermore reasonable and necessary or medically-indicated for the Medicare population.

42. Accordingly, CMS has consistently expressed in its rulemaking process its own expectation that drug products for which it pays under Medicare not be "adulterated, misbranded, spoiled, contaminated, expired, or counterfeit." *See* Medicare Program: Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B, 70 Fed. Reg. 10746, 10759 (Mar. 4, 2005); *same*, 70 Fed. Reg. 39022, 39060 (July 6, 2005); Medicare

[3] http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs-Items/CMS012673.html

Program: Revisions to [] Certain Provisions Related to the Competitive Acquisition Program of Outpatient Drugs and Biologicals Under Part B, 70 Fed. Reg. 70116, 70244 (Nov. 21, 2005). In particular, CMS has in various circumstances affirmed that Medicare will not pay for drugs that have been adulterated or misbranded. *See, e.g.,* Medicare Benefit Policy Manual, *Denial of Medicare Payment for Compounded Drugs Produced in Violation of Food, Drug and Cosmetic Act*, Ch. 15, § 50.4.7 ("… Medicare does not pay ... if FDA determines that a required NDA has not been approved or that the drug is misbranded or adulterated…") (emphasis added).[4]

43. Eligibility for Government payment of drug products under Medicare is thus fully integrated with the Government's requirements, specifications and standards under the FDCA, including Government approval to market the drug product.

44. Compliance of the drug product with the FDCA and its initial and continuing status as an FDA "approved" drug are conditions of participation in and of payment under Medicare.

45. As alleged below, Gilead caused false claims for payment to be submitted under Medicare for the Affected Drug Products, which were not approved by the Government for marketing under the FDCA.

b. Medicaid

46. Medicaid is the nation's medical assistance program for the needy, the medically-needy aged, blind, and disabled and families with dependent children. 42 U.S.C. §§ 1396-1396v. Medicaid is funded by a combination of Government and State funds; approximately 57% of Medicaid funding is provided by the Government. CMS and the FDA also jointly administer Medicaid for the Government.

47. Among other forms of medical assistance, the Medicaid programs cover outpatient prescription drugs. 42 U.S.C. §§ 1396a(10)(A) & 1396d(a)(12). Reimbursement under Medicaid for such a drug product purchase is limited to a "covered outpatient drug,"

[4] http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c15.pdf

which is statutorily defined as a drug "which is approved for safety and effectiveness as a prescription drug" under the FDCA. 42 U.S. C. § 1396r–8(k)(2).

48. Furthermore, to have their drug products participate in the Medicaid (and Medicare) programs, drug manufacturers must enter into rebate agreements directly with the Secretary of HHS requiring them to pay rebates to Medicaid programs according to a statutory formula. The Sample Rebate Agreement[5] by its terms likewise applies only to a "Covered Outpatient Drug," which is again defined as set forth in 42 U.S. C. § 1396r–8(k)(2) -- that is, a drug "approved for safety and effectiveness" as a prescription drug under the FDCA.

49. Eligibility for Government payment for drug products under Medicaid is thus fully integrated with the Government's requirements, specifications and standards under the FDCA, including securing FDA approval to market the drug product.

50. Indeed, when the Government approves an NDA or PAS for a pharmaceutical drug, by statute the approval is made by the Secretary of HHS rather than an FDA official. 21 U.S.C. §§ 355, 356a and 321(d). Likewise, where reimbursement is allowed for a "covered outpatient drug" that is not approved for safety and effectiveness under the FDCA, by statute the determination is made by the Secretary of HHS rather than an official of CMS. 42 U.S.C § 1396r-8(k)(2).

51. Compliance of the drug product with the FDCA and its initial and continuing status as an FDA "approved" drug are conditions of participation in and of payment under Medicaid.

52. As alleged below, Gilead caused false claims for payment to be submitted under Medicaid for the Affected Drug Products, which were not approved by the Government for marketing under the FDCA.

[5] *See* Sample Rebate Agreement available at http://www.medicaid.gov/medicaid-chip-program-information/by-topics/benefits/prescription-drugs/national-drug-rebate-agreement.html.

c. TRICARE

53. TRICARE (formerly known as CHAMPUS) is the DOD's health insurance program for active military personnel, military retirees, and their dependents, and is codified at 10 U.S.C. § 1071 *et seq*; 32 C.F.R. § 199 *et seq.* TRICARE is administered for the Government by the Department of Defense Military Health System.

54. DOD regulations for the TRICARE program provide:

> The term "abuse" generally describes incidents and practices which may directly or indirectly cause financial loss to the Government under CHAMPUS or to CHAMPUS beneficiaries. For the definition of abuse, see § 199.2 of this part. The type of abuse to which CHAMPUS is most vulnerable is the CHAMPUS claim involving the overutilization of medical and health care services. To avoid abuse situations, ***providers have certain obligations to provide services and supplies under CHAMPUS which are***: Furnished at the appropriate level and only when and to the extent medically necessary as determined under the provisions of this part; ***of a quality that meets professionally recognized standards of health care***; and, supported by adequate medical documentation as may reasonably be required under this party by the Director, OCHAMPUS, or a designee, to evidence the medical necessity and quality of services furnished, as well as the appropriateness of the level of case. ***A provider's failure to comply with these obligations can result in sanctions being imposed by the Director, OCHAMPUS, or a designee, under this section. Even when administrative remedies are not initiated under this section, abuse situations under CHAMPUS are a sufficient basis for denying all or any part of CHAMPUS cost-sharing of individual claims….***

32 C.F.R. § 199.9(b) (emphasis added). DOD regulations further provide:

> For purposes of this part, abuse is defined as any practice that is inconsistent with accepted sound fiscal, business, or professional practice which results in a CHAMPUS claim, unnecessary cost, or CHAMPUS payment for services or supplies that are: (1) not within the concepts of medically necessary and appropriate care, as defined in this part, or (2) that fail to meet professionally recognized standards for health care providers. The term "abuse ***includes deception or misrepresentation by a provider, or any person or entity acting on behalf of a provider in relation to a CHAMPUS claim.***")

32 C.F.R. § 199.2(b) (emphasis added).

55. "Medically necessary and appropriate care" and "professionally recognized standards for health care providers" as used in the foregoing TRICARE regulations mean and include FDCA requirements, specifications and standards for drug products reimbursed through TRICARE, including the cGMPs. Indeed, the DOD specifically describes its pharmacy benefit

program as providing "outpatient coverage to beneficiaries for medications that are ***approved for marketing*** by the U.S. Food and Drug Administration (FDA) and that generally require prescriptions." (emphasis added). TRICARE Pharmacy Program Handbook, p. 13.[6]

56. Furthermore, as a precondition to participation in and payment under TRICARE, drug manufacturers must sign a written agreement with DOD obligating them honor certain pricing standards. 32 C.F.R. § 199.21(q)(2)(i). To be a "covered drug" eligible for payment under TRICARE, the product must again be "approved for safety and effectiveness" as a prescription drug under the FDCA. 32 C.F.R. § 199.21(q)(2)(iii) and 38 U.S.C. § 8126(h)(2).

57. Eligibility for Government payment for drug products purchased under TRICARE is thus fully integrated with the Government's requirements, specifications and standards under the FDCA, including securing FDA approval to market the drug product.

58. Compliance of the drug product with the FDCA and its initial and continuing status as an FDA "approved" drug are conditions of participation in and of payment under TRICARE.

59. As alleged below, Gilead caused false claims for payment to be submitted under TRICARE for the Affected Drug Products, which were not approved by the Government for marketing under the FDCA.

d. FEHBP

60. FEHBP is a Government health insurance program for federal employees, retirees, and their dependents. 5 U.S.C. § 8901 *et seq.*; 5 C.F.R. ch. 1, part 890-891. It is administered for the Government by the Office of Personnel Management ("the Office").

61. The Federal Employee Health Benefits Act of 1959 contains certain mandates by which a provider of health care services or supplies must abide in order to remain eligible for participation or continued participation in the program:

> The Office may bar the following providers of health care services from participating in the program under this chapter: [¶] Any provider that the Office

[6] http://tricare.mil/pharmacy

> determines, in connection with claims presented under this chapter, has … charged for health care … supplies … which are of a quality that fails to meet professionally recognized standards for such services or supplies.

5 U.S.C. § 8902a(c)(4). The Office may bar a provider from participating in the program and also impose a civil monetary penalty:

> Whenever the Office determines [¶] that a provider of health care services or supplies has knowingly made, or caused to be made, and false statement or misrepresentation of a material fact which is reflected in a claim presented under this chapter.

5 U.S.C. § 8902a(d)(2).

62. "Professionally recognized standards" for drug products as used in 5 U.S.C. § 8902a(c)(4) means and includes FDCA requirements, specifications and standards, including cGMP. If a drug product is withdrawn from the market by the FDA it is withdrawn from the FEHBP formulary.

63. Eligibility for Government payment for drug products under FEHBP is thus integrated with the Government's requirements, specifications and standards under the FDCA, including securing FDCA approval to market the drug product.

64. Compliance of the drug product with the FDCA and its initial and continuing status as an FDA "approved" drug are conditions of participation in and of payment under FEHBP.

65. As alleged below, Gilead caused false claims for payment to be submitted under FEHBP for the Affected Drug Products, which were not approved by the Government for marketing under the FDCA.

e. Ryan White Program

66. The Ryan White HIV/AIDS Program, first authorized in 1990, is funded at $2.32 billion in fiscal year 2014. The Program is administered for the Government by the HHS, Health Resources and Services Administration (HRSA), HIV/AIDS Bureau (HAB).

67. Part B of the Ryan White HIV/AIDS Treatment Extension Act of 2009 (Public Law 111-87) provides grants to States to improve the quality, availability, and organization of

HIV/AIDS health care and support services. Part B grants include a base grant, the AIDS Drug Assistance Program ("ADAP") award, and ADAP Supplemental Drug Treatment Program funds.

68. The ADAPs provide prescription medications that have been approved for marketing by the FDA for eligible people with HIV who have limited or no prescription drug coverage or who need assistance with insurance premiums and cost-sharing. The ADAP in each State is unique in that it decides which medications will be included in its formulary and how those medications will be distributed. 42 U.S.C. § 300ff-26. However, each state grantee must cover all classes of core antiretroviral drugs listed by the HHS on their ADAP formulary. 42 U.S.C. § 300ff-26(c)(1). HHS, in turn, has listed only HIV antiretroviral drugs approved for marketing by the FDA.

69. Eligibility for Government payment for drug products under Ryan White is thus integrated with the Government's requirements, specifications and standards under the FDCA, including securing FDCA approval to market the drug product.

70. Compliance of the drug product with the FDCA and its initial and continuing status as an FDA "approved" drug are conditions of participation in and of payment under Ryan White.

71. As alleged below, Gilead caused false claims for payment to be submitted under Ryan White for the Affected Drug Products, which were not approved by the Government for marketing under the FDCA.

2. Government Direct Pay Programs

72. The Federal Acquisition Regulations System has been established for the codification and publication of uniform policies and procedures for acquisition by all executive agencies of the Government. The Federal Acquisition Regulations System consists of the Federal Acquisition Regulation (FAR), 48 C.F.R. 1.101 *et seq.*, which is the primary document, and agency acquisition regulations that implement or supplement the FAR.

73. The Government has under the FAR assigned Government-wide responsibility for quality assurance of drug products acquired by the Government to the FDA. The FAR provides in pertinent part:

> **46.408 Single-agency assignments of Government contract quality assurance.**
>
> (a) Government-wide responsibility for quality assurance support for acquisitions of certain commodities is assigned as follows:
>
> (1) For drugs, biologics, and other medical supplies — the Food and Drug Administration; ***

48 C.F.R. § 46.408.

74. The acquisition of drug products by the Government is, therefore, jointly administered by the acquiring agency and the FDA. The Government is both the payor and the assessor of the eligibility for payment of the drug products as delivered.

75. Beyond this general integration of responsibility, several individual agencies of the Government have even more specifically expressed their reliance on the FDA to determine the conditions of payment under their direct purchase programs.

a. Department of Defense

76. The Government through the DOD also makes direct purchases of drug products from manufacturers like Gilead.

77. The DOD's purchase of drug products is governed by a Memoranda of Understanding (MOU 225-97-4000), in which the DOD relies on FDA approval to establish quality assurance for the drug products purchased. The MOU between the DOD and the FDA

furthermore reiterates that the "FDA provides the quality assurance support for D[O]D centrally managed contracts for drugs…"

78. In addition, the MOU expressly adopts cGMP as the standard applicable to the manufacture of drug products paid for by the DOD:

> The [FDA] Good Manufacturing Practice Regulations will be the quality standard applied to industry for the manufacturing, processing, packaging or holding of medical products acquired on government contracts. The FDA will be the agency responsible for the administrative interpretation and enforcement of these statutes and regulations.

79. Eligibility for Government payment for drug products purchased by the DOD is thus fully integrated with the Government's requirements, specifications and standards under the FDCA, including securing FDA approval to market the drug product.

80. Compliance of the drug product with the FDCA and its initial and continuing status as an FDA "approved" drug are conditions of participation in and of payment by the DOD.

81. As alleged below, Gilead caused false claims for payment to be submitted to the VA for the Affected Drug Products.

b. Department of Veterans Affairs

82. The Government through the VA provides medical assistance, including prescription drug coverage, for persons who have been discharged from active duty service in the military, naval, or air service.

83. The Government's purchase of drug products by the VA is governed by Memoranda of Understanding (MOU 224-76-8049), in which the VA relies on FDA approval to establish quality assurance for the drug products purchased by it. The MOU between the VA and the FDA reiterates that "FDA will be responsible for quality assurance for all drugs … VA purchases, stores and distributes…"

84. The MOU also expressly provides that the FDA's Current Good Manufacturing Practice Regulations "will be the single standard to be applied industry-wide for the manufacture, processing, packing or holding of drugs procured by governmental agencies." [7]

85. Eligibility for Government payment for drug products purchased by the VA is thus fully integrated with the Government's requirements, specifications and standards under the FDCA, including securing FDA approval to market the drug product.

86. Compliance of the drug product with the FDCA and its initial and continuing status as an FDA "approved" drug are conditions of participation in and of payment by the VA.

87. As alleged below, Gilead caused false claims for payment to be submitted to the VA for the Affected Drug Products, which were not approved by the Government for marketing under the FDCA.

c. Federal Bureau of Prisons

88. The Government through the BP operates a health system designed to ensure that federal offenders serve their sentences of imprisonment in facilities that are safe, humane, cost-efficient, and appropriately secure, and provide reentry programming to ensure their successful return to the community. The Health Services Division is responsible for medical, dental, and mental health (psychiatric) services provided to Federal inmates in BP facilities, including health care delivery, infectious disease management, and medical designations.

89. BP acquisitions are governed by, among other things, the FAR assigning responsibility for quality assurance of drug products purchased by BP to the FDA. 48 C.F.R. § 46.408.

90. Eligibility for Government payment for drug products purchased by the BP is thus fully integrated with the Government's requirements, specifications and standards under the FDCA, including securing FDA approval to market the drug product.

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[7] http://www.fda.gov/AboutFDA/PartnershipsCollaborations/MemorandaofUnderstandingMOUs/DomesticMOUs/ucm112558.htm.

91. Compliance of the drug product with the FDCA and its initial and continuing status as an FDA "approved" drug are conditions of participation in and of payment by the BP.

92. As alleged below, Gilead caused false claims for payment to be submitted to the BP for the Affected Drug Products, which were not approved by the Government for marketing under the FDCA.

d. USAID (PEPFAR)

93. The Government through USAID makes direct purchase of drug products for distribution thorough "The President's Emergency Plan for Aids Relief ("PEPFAR"), a Government relief program designed, in part, to provide funding for the procurement and distribution of HIV/AIDS pharmaceuticals. 22 U.S.C. § 7601 *et seq.* Under PEPFAR, the Government through USAID purchases HIV/AIDS pharmaceuticals and other products for distribution in 120 countries in Africa and around the globe.

94. The USAID's "Eligibility of Commodities" rules (ADS Chapter 312) state as an objective "[t]o assure that only safe and efficacious pharmaceutical products are financed [and] that they are manufactured in accordance with the accepted quality standards,…" Section 312.2.3.

95. "Accepted quality standards" for drug products as used within Section 312.2.3 means and includes FDCA requirements, specifications and standards, including the cGMPs.

96. Suppliers to USAID must furthermore sign a "Supplier's Certificate and Agreement" for project commodities with USAID in which, among other things, the supplier certifies that the commodity supplied "meets the source, origin componentry and nationality requirements in the contract…." AID Form 1450-4.

97. Suppliers are also required to agree to make an appropriate refund to USAID in the event that any of the terms of the certificate and agreement with USAID (e.g., Form 1450-4) are violated. ADS Ch. 324, Section E324.5.8c.

98. Eligibility for Government payment for drug products under PEPFAR is thus fully integrated with the Government's requirements, specifications and standards under the FDCA, including securing FDA approval to market the drug product.

99. Compliance of the drug product with the FDCA and its initial and continuing status as an FDA "approved" drug are conditions of participation in and of payment under PEPFAR.

100. As alleged below, Gilead caused false claims for payment to be submitted under PEPFAR for the Affected Drug Products, which were not approved by the Government for marketing under the FDCA.

e. Public Health Service

101. The PHS provides funding, including outpatient drug coverage, for entities such as black lung clinics, AIDS drug purchasing assistance programs, hemophilia diagnostic treatment centers, urban Indian organizations, disproportionate share hospitals, and other entities listed in § 340B(a)(4) of the Public Health Service Act, 42 U.S.C. § 256b.

102. "Covered outpatient drugs" eligible for participation in the program are defined the same as in 42 U.S.C. 1396r–8(k)(2): that is, a drug "which is approved for safety and effectiveness" as a prescription drug under the FDCA. 42 U.S.C. § 256b(b)(1).

103. Eligibility for Government payment for drug products by the Public Health Service is thus integrated with the Government's requirements, specifications and standards under the FDCA, including securing FDCA approval to market the drug product.

104. Compliance of the drug product with the FDCA and its initial and continuing status as an FDA "approved" drug are conditions of participation in and of payment by the Public Health Service.

105. As alleged below, Gilead caused false claims for payment to be submitted to the Public Health Service for the Affected Drug Products, which were not approved by the Government for marketing under the FDCA.

C. CONDITIONS FOR DRUG PRODUCT PARTICIPATION IN AND PAYMENT UNDER THE GOVERNMENT PAYMENT PROGRAMS

1. NDA Approval

106. Approval by the FDA of both the drug formulation and method of manufacture is required for introduction of the drug in interstate commerce and distribution for human use. FDA regulations promulgated under the FDCA provide that NDA applications to the FDA for approval of new drugs must include: "…. (B) a full list of the articles used as components of such drug; (C) a full statement of the composition of such drug; (D) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug[.]" 21 U.S.C. §§ 355(b)(1)(B)-(D).

107. To obtain approval to market a drug product each drug product, the manufacturer must in the NDA also certify that, if the application is approved, that it "agree[s] to comply with all applicable laws and regulations that apply to approved applications, including, but not limited to … Good manufacturing practice regulations in 21 CFR Parts 210." Form FDA 356h ("Form 356h").

108. Compliance with the FDCA's NDA approval process is not waivable by the FDA; in other words, the FDA has no discretion to allow in interstate commerce new drug products before a properly validated NDA is approved.

109. Moreover, NDA approval premised on untrue statements of material fact is invalid under the FDCA, which mandates that the Secretary of HHS "shall … withdraw approval of an application with respect to any drug under this section if the Secretary finds … that the application contains any untrue statement of a material fact…." 21 U.S.C. § 355(e).

2. Certifications of Compliance Generated during the Manufacturing Process

110. The cGMP require testing of an API before it is used by a drug manufacturer or a contract manufacturing organization ("CMO") unless the API supplier has been qualified to perform the testing and has provided a report of its own analysis, known as a "Certificate of Analysis" ("COA"), which confirms the API was manufactured (a) in compliance with the applicable FDA approved componentry specifications (values/limits/ranges) for the API, and (b)

in compliance with cGMP. 21 C.F.R. § 211.84(d)(2). *See* Guidance for Industry: Q7A Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients, at 29.[8]

111. In addition, for each batch of finished drug product released into interstate commerce a manufacturer may generate a Material Status Notification ("MSN") or similar statement in which it certifies adherence to the conditions of Government FDCA approval, including an express certification that the product was "manufactured and tested in compliance with all current GMP regulations, and … in accordance with approved manufacturing processes and specifications."

112. Compliance with the FDCA's cGMP and documentation requirements in the drug manufacturing process is not waivable by the FDA; in other words, the FDA has no discretion to allow a manufacturer to release for commercial sale a drug product that was not manufactured in compliance with the requirements of cGMP, including COA testing, documentation and certification requirements.

3. Manufacturing Site Registration Process

113. The FDCA requires that every person, domestic or foreign, "upon first engaging" in the manufacture, preparation, propagation, compounding or processing of a drug API must register with the Government. 21 U.S.C. § 360(c) & (i).

114. Regulations promulgated by the FDA under the FDCA accordingly require every person "upon first engaging in the manufacture, preparation, propagation, compounding, or processing of a drug or drugs … in any establishment which he owns or operates in any State shall immediately register with [HHS]," and provide the name of such person, places of business of such person, all such establishments, and the unique facility identifier of each such establishment. 21 C.F.R § 360(c).

115. The regulations likewise require immediate registration of foreign facilities with the FDA. 21 C.F.R § 360(i).

[8] http://www.fda.gov/downloads/Drugs/.../Guidances/ucm073497.pdf.

116. Government regulations promulgated by the FDA flatly prohibit the importation of any drug or API into the United States unless it is manufactured, prepared or processed at a registered foreign drug establishment. 21 C.F.R. § 207.40(b).

117. As alleged above, through its COAs the manufacturer of a drug product must certify that a drug product's API has been legally sourced from a registered facility with a demonstrated capability to meet FDA production and quality standards. "Guidance for Industry: Q7A Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients," at 29.[9]

118. Compliance with the FDCA in registering the drug manufacturing facility is not waivable by the FDA; in other words, the FDA has no discretion to allow a manufacturer to use API manufactured at an unregistered facility.

4. PAS Approval

119. The FDCA (21 U.S.C. § 356a) and FDA regulations (21 C.F.R. §§ 314.70 and 314.81, respectively) require drug manufacturers to obtain FDA approval for, or make the FDA aware of, post-approval deviations from the conditions established in an approved NDA.

120. When a manufacturer alters the NDA approved manufacturing process in a way that has a "substantial potential to have an adverse effect on the identity, strength, quality, purity, or potency of the drug product" ("a major change"), the manufacturer must submit and obtain Government approval of a PAS. 21 U.S.C. § 356a; 21 C.F.R. § 314.70(b)(1); *see* generally, "Guidance for Industry: Changes to an Approved NDA or ANDA (rev. 1, April 2004);[10] "Guidance for Industry: Changes to an Approved NDA or ANDA, Questions and Answers (Jan. 2001)."[11]

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[9] http://www.fda.gov/downloads/Drugs/.../Guidances/ucm073497.pdf

[10] http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm077097.pdf

[11] http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm122871.pdf

121. Such "major changes" include "changes in the qualitative or quantitative formulation of the drug product, including inactive ingredients, or in the specifications provided in the approved application." 21 C.F.R. § 314.70(b)(2)(i).

122. Such "major changes" also include "[c]hanges in the … manufacture of the drug substance [API] that may affect the impurity profile and/or the physical, chemical or biological properties of the [API];"…" 21 C.F.R. § 314.70(b)(2)(iv). A major change requiring a PAS therefore includes obtaining API from a manufacturing facility that has does not have a satisfactory cGMP inspection or has never before been inspected by the FDA. *See* "Guidance for Industry: Changes to an Approved NDA or ANDA (rev. 1, April 2004)," at 9; "Guidance for Industry: Changes to an Approved NDA or ANDA, Questions and Answers (Jan. 2001)," at 2-3. In such instances, the PAS application requires the manufacturer to conduct testing and provide the FDA with evidence establishing both (a) that the new facility is able to manufacture API equivalent to that produced elsewhere, and (B) that the safety and efficacy of the manufacturer's previously approved drug product will not be adversely affected.

123. As part of a PAS, therefore, the applicant is required by law to provide certain information, including: "(i) A detailed description of the proposed change; (ii) The drug product(s) involved; (iii) The manufacturing site(s) or area(s) affected; (iv) A description of the methods used and studies performed to assess the effects of the change; (v) The data derived from such studies." 21 C.F.R. § 314.70(b)(3)(i)-(v).

124. For all major changes, the PAS applicant must submit and receive FDA approval of the supplemental application to the NDA ***before*** distribution "of the drug so made":

> [A] drug made with a major manufacturing change may be distributed ***only if, before the distribution of the drug so made***, the holder involved submits to the Secretary a supplemental application for such change ***and the Secretary approves the application.***

21 U.S.C. § 356a(c)(1) (emphasis added); *see also*, 21 C.F.R. § 314.70(a)(2); "Guidance for Industry: Changes to an Approved NDA or ANDA (rev. 1, April 2004)," at 3 ("A major change requires the submission of a supplement and approval by FDA prior to distribution of the drug

product made using the change."); *accord*, "Guidance for Industry: Changes to an Approved NDA or ANDA, Questions and Answers (Jan. 2001)," at 2; *see also*, "Guidance for Industry: CMC Postapproval Manufacturing Changes to Be Documented in Annual Reports (March 2014),"[12] at 2.

125. When a pharmaceutical company seeks to begin using a new API manufacturing site via a PAS application, therefore, it is prohibited by law from distributing drug product manufactured using the API generated at the new facility prior to obtaining the FDA's approval for the change. 21 U.S.C. §356a(c); 21 C.F.R. § 314.70(b)(3). API process validation is a requirement both before placing the API into a finished drug product, and before placing the finished drug product into interstate commerce. FDA Compliance Policy Guide, Sec. 490.100, Process Validation Requirements for Drug Products and Active Pharmaceutical Ingredients Subject to Pre-Market Approval.[13]

126. Compliance with the FDCA's PAS requirement is not waivable by the FDA; in other words, the FDA has no discretion to allow a manufacturer to release a drug product made with a major change requiring submission of a PAS before submitting and obtaining Government approval of the PAS. By the same token, absent submission and Government approval of the PAS for a new manufacturing facility, no drug product "so made" with the change is "approved for safety and effectiveness as a prescription drug" under the FDCA and any prior "approval of an" NDA based test performed at a different facility is "not effective with respect to such drug" produced at the new facility under 21 U.S.C. § 355(a).

[12] http://www.fda.gov/downloads/Drugs/.../Guidances/UCM217043.pdf

[13] http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm074411.htm

D. GOVERNMENT PROHIBITION OF "ADULTERATED" AND "MISBRANDED" DRUGS

127. No drug product may lawfully be released for commercial sale in interstate commerce except as permitted by the Government under the FDCA.

128. Under the FDCA, the following actions are prohibited: (1) "[t]he introduction or delivery for introduction into interstate commerce of any … drug … that is adulterated," 21 U.S.C. § 331(a); (2) "[t]he adulteration … of any … drug … in interstate commerce," 21 U.S.C. § 331(b); (3) "[t]he receipt in interstate commerce of any … drug … that is adulterated[,] … and the delivery or proffered delivery hereof for pay or otherwise," 21 U.S.C. § 331(c); and (4) "[t]he manufacture within any Territory of any … drug … that is adulterated," 21 U.S.C. § 331(g).

129. The FDCA defines "adulteration" to include any drug that "purports to be or is represented as a drug the name of which is recognized in an official compendium, and its strength differs from, or its quality or purity falls below, the standard set forth in such compendium." 21 U.S.C. §351(b).

130. The Government also defines "adulteration" to include a drug for which "the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice [cGMP] to assure that such drug meets the requirements of this chapter as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess…." 21 U.S.C. § 351(a)(2)(B).

131. The Government by FDA regulation has explicitly adopted the cGMPs under the FDCA, which likewise render a drug product "adulterated" for noncompliance "in the manufacture, processing, packing, or holding of a drug." 21 C.F.R. § 210.1(a). The cGMPs contain the minimum requirements that pharmaceutical companies must meet in manufacturing, processing, packing, and holding drugs to assure that they meet the safety, identity, strength, quality, and purity characteristics that they purport to possess.

132. In short, drug products are deemed to be "adulterated" if they are not manufactured in compliance with the cGMPs. 21 U.S.C. §§ 351(a)(2)(B).

133. Because no distinction is made between APIs and finished drug products in the FDAC, APIs are subject to the adulteration provisions of the FDCA, and the failure of either to comply with cGMP constitutes a violation of the FDCA. FDA Compliance Program Guidance Manual, Chapter 56 – Drug Quality Assurance, at p. 4.[14]

134. The Government furthermore deems a drug product "misbranded" under 21 U.S.C. § 352(o) if it "was manufactured, prepared, propagated, compounded, or processed in an establishment not duly registered under" the FDCA, which as alleged above requires foreign manufacturers to "immediately" register with the Government to allow validation testing and a qualifying inspection of the facilities by the FDA. 31 U.S.C § 360(i).

135. Drug products or API that are either "adulterated" and/or "misbranded" under the FDCA are subject to seizure by the Government. *See United States v. Articles of Drug Labeled Colchicine*, 442 F.Supp. 1236 (S.D.N.Y.1978) (lots and packets of drugs would be forfeited on the ground that they were adulterated and misbranded because they were prepared, packaged and held under conditions not in conformity with good manufacturing practice, and the facilities and controls in their processing, packaging and holding were not operated so as to assure that the drugs met statutory requirements as to safety, identity, strength, quality and purity characteristics).

136. "Adulterated" or "misbranded" material seized by the Government are normally not offered for sale after seizure, but instead are "destroyed by burning, burial, or dumping" in a manner appropriate under the National Environmental Policy Act and that ensures the product

[14] http://www.fda.gov/downloads/ICECI/ComplianceManuals/CompliancePrograManual/UCM125420.pdf

cannot be retrieved. FDA Regulatory Procedures Manual § 6-1-9, *Disposition of Seized Articles*.[15]

E. MATERIALITY OF FDCA COMPLIANCE UNDER THE GOVERNMENT PAYMENT PROGRAMS

137. As alleged above, the Government prohibits in interstate commerce drug products (a) that are not "approved for safety and effectiveness" by the Government under the FDCA, (b) that are "adulterated" or "misbranded" within the meaning of the FDCA, or (c) that do not otherwise comply with the Government's manufacturing requirements, specifications and standards under the FDCA, including cGMP.

138. The failure of a drug product to be "approved for safety and effectiveness" under the FDCA is material to the decision of the Government and the States to pay for the drug product under the Government Payment Programs, as it has "a natural tendency to influence, or be capable of influencing, the payment … of money" under those programs. 31 U.S.C. § 3729(b)(4).

139. The status of a drug product as "adulterated" or "misbranded" under the FDCA is material to the decision of the Government and the States to pay for the drug product under the Government Payment Programs, as it has "a natural tendency to influence, or be capable of influencing, the payment … of money" under those programs. 31 U.S.C. § 3729(b)(4).

140. The failure of a drug product to be manufactured in compliance with cGMP under the FDCA is material to the decision of the Government and the States to pay for the drug product under the Government Payment Programs, as it has "a natural tendency to influence, or be capable of influencing, the payment … of money" under those programs. 31 U.S.C. § 3729(b)(4).

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[15] http://www.fda.gov/iceci/compliancemanuals/regulatoryproceduresmanual/ucm176733.htm#SUB6-1-9

141. The use of API in a drug product sourced from an unregistered foreign manufacturing establishment in violation of the FDCA is material to the decision of the Government and the States to pay for the drug product under the Government Payment Programs, as it has "a natural tendency to influence, or be capable of influencing, the payment … of money" under those programs. 31 U.S.C. § 3729(b)(4).

142. Accordingly, the Government has pursued claims under the FCA specifically to recover from drug product manufacturers for payments made under the Government Payment Programs for drug products that were not validly approved or manufactured at non-registered facilities, including:

- *U.S. v. Ranbaxy Laboratories, Ltd. et al*, Civ. JFM 12-CV-0250 (D. Md.) (false data allegedly submitted for FDA approval of contaminated drugs manufactured in foreign facility and paid for under Government Payment Programs); and
- *U.S. et al. v. SmithKlineBeecham Corp. et al.*, Case No. 04 CV10375 (JLT) (Medicaid claims were allegedly false and fraudulent because the drugs, which were manufactured at defendants' plant in Puerto Rico, were not manufactured in accordance with FDA approved processes, and/or did not come with the assurance of identity, strength, quality and purity required for distribution to patients, and/or approvals for the drugs were obtained through false representations to the FDA).

F. GILEAD'S WRONGFUL ACTS

1. Summary

143. Gilead manufactures a number of drug products, particularly those for the treatment of HIV/AIDS, which are extremely expensive and therefore typically paid for by the Government. However, as alleged above, the Government Payment Programs will pay only for drug products that the Government has approved under and that otherwise comply with the FDCA.

144. Gilead through the NDA process obtained Government NDA approval for several of its drug products in which the API is emtricitabine ("FTC"), including Emtriva, Emtriva Oral Powder, Truvada and Atripla. But, as alleged above, any change in the manufacturing of an NDA approved drug product that has a substantial potential for an adverse effect on the identity, strength, quality, purity, or potency of the drug product requires further Government approval through a PAS ***before*** distribution of the drug product made using the

change. Two such "major changes" are relevant here: (1) a change that potentially affects the quality and purity of the drug product's API and (2) a move to a different manufacturing site that has never been inspected by the Government for compliance with cGMP. No drug product made under either such changed condition is approved for safety and effectiveness under the FDCA absent Government approval of a properly documented and truthful PAS.

145. As alleged in further detail below, Gilead by approximately 2006 had obtained FTC [redacted] from a "shadow source" in China; specifically, an unregistered, uninspected and unapproved manufacturing site known as Synthetics China Plant 202 ("SC Plant 202"). Gilead ordered an enormous amount of FTC from SC Plant 202 which it fraudulently designated has having been manufactured at a registered establishment in Korea ("Yuhan"). Gilead used unregistered SC Plant 202 FTC in its drug products released for commercial sale, including the Affected Drug Products.

146. Gilead's use of Yuhan as a shadow establishment to conceal its use of API manufactured at the unregistered non-approved SC Plant 202 as a subterfuge to smuggle the Chinese API into commerce is memorialized in Gilead's internal [redacted] attached hereto as Exhibits 7 and 8. [redacted]

147. Not only was the SC Plant 202 facility unregistered and uninspected, but the two of the first three validation batches of FTC tested were found to be contaminated and otherwise failed to comply with the conditions of the NDAs that Gilead had previously submitted in connection with its drugs containing FTC.

148. Recognizing that use of API from SC Plant 202 was a "major change" requiring the Government approval of the drug products made using its FTC, Gilead submitted a PAS application to the Government to secure approval of drug products using SC Plant 202 as a sources of FTC. In the initial PAS, however, Gilead used falsified validation data and falsified COAs, concealing the failed validation batches. Gilead subsequently submitted an amended PAS, in which it substituted validation batches. The FDA approved the amended PAS based on Gilead's falsified validation data in May 2009, but SC Plant 202 was not registered under the FDCA until the first quarter of 2010.

149. Gilead used the contaminated validation batches and all of the remaining SC Plant 202-sourced FTC in commercial releases of its drug products, both before and after its submission of the fraudulent PAS. To do so, Gilead generated a series of false statements, records and certifications concealing the true source of and impurities in the Chinese-sourced FTC.

150. Gilead repeated the process a short time later, when it purchased additional large quantities of FTC from another, larger unregistered and uninspected Synthetics China plant ("SC Plant 203"). Gilead again found this FTC to be contaminated, and "inactivated" Synthetics China as an FTC supplier in October 2011. Gilead nevertheless sent the FTC sourced from SC Plant 203 to its contract manufacturing organization ("CMO") Patheon, for use in manufacturing it final drug product. When Patheon too reported contamination in the FTC, Gilead set on a plan to fraudulently salvage the SC Plant 203 FTC. Gilead arranged for the FTC to be transferred to Gilead Alberta, where a batch record was modified and the API material was eventually reworked by physically sieving the material without notice to or approval of the FDA, and given a new inventory control number falsely identifying Gilead Alberta as its source. Gilead then used the contaminated SC Plant 203 FTC in its drug products released for commercial sale, including the Affected Drug Products.

151. Gilead's use of API sourced from unapproved sites was not limited to Synthetics China plants. For example, Gilead deliberately began using Gilead Alberta in June 2007 to

manufacture batches of ambrisentan ("AMB"), the active ingredient in the drug Letairis, before submitting (let alone obtaining Government approval of) a PAS to do so. When Mr. Campie learned of what transpired, he instructed that the batches of Letairis containing the Gilead Alberta API that had been manufactured and shipped to inventory at Gilead, San Dimas be removed from the company's supply chain and placed into quarantine until Gilead received Government approval to place them into the stream of commerce, in accordance with FDA regulations, 21 C.F.R. § 314.70. Yet Gilead overruled this decision, and ordered that the quarantined Letairis batches be once again placed into approved status for commercial distribution. In July 2009, four months before the FDA responded to Gilead's supplemental application and approved Gilead Alberta as a manufacturing site, Gilead approved the release for commercial sale of numerous commercial lots of Letairis incorporating the Gilead Alberta-manufactured API.

152. Because the Affected Drug Products for which the Government paid containing the FTC sourced from SC Plant 202 and SC Plant 203 and the AMB sourced from Gilead Alberta were not approved under the FDCA, they were not eligible for payment under the Government Payment Programs. Gilead had thus, through its false statements, records and certifications, caused the submission of false claims that the Affected Drug Products were in fact approved under the FDCA, when they were not. Indeed, not only were the Affected Drug Products not "approved," they constituted "adulterated" and "misbranded" drugs within the meaning of the FDCA, which were not manufactured in accordance with cGMP and contained API that was not sourced from a registered facility. The Affected Drug Products were thus essentially contraband under the FDCA -- not only ineligible for payment under the Government Payment Programs but prohibited from being released into interstate commerce and subject to seizure by the Government.

2. Gilead Illegally Sources FTC from Synthetics China

153. In approximately December of 2008 Mr. Campie encountered a Gilead request for approval (via an internal Commercial Change Implementation Plan ("CCIP") document) to

use a Chinese facility as a CMO to manufacture FTC, the API in many of Gilead's HIV/AIDS drug products, including Emtriva, Emtriva Oral Solution, Truvada, and Atripla. The CCIP stated that Gilead had used Synthetics China as a source of the raw materials in FTC for 4 years, even though Synthetics China had no FDA inspection history. Gilead assigned Internal Control Number "ICN-034" to Synthetics China FTC.

154. [redacted]

155. Mr. Campie had not reviewed the PAS submission to the FDA as part of his job duties and had not participated in preparing the application as he was at the time being effectively circumvented in the review/approval process. (A year earlier, Mr. Campie had documented his concerns to his manager regarding the quality of the API used in Gilead drugs.) Mr. Campie only learned of the plan's existence because someone in the Gilead Canada office had erroneously listed his name as a reviewer on the submission to the Canadian regulatory authority. Indeed, while Mr. Campie's regular job duties focused on commercial drug product quality assurance/control issues – he was (based on job requirements) expected to review API submissions as well.

156. Gilead's plan to use a new Chinese CMO greatly concerned Mr. Campie, as he saw parallels between Gilead's conduct and recent news coverage on another pharmaceutical

company that had sourced adulterated API from an unapproved Chinese CMO which resulted in a hundreds of reports of serious injury and scores of patient deaths. Also, Synthetics China had no existing U.S. customers. Moreover, Gilead's revenue from Government payments for Gilead's affected anti-HIV drugs amounted to billions of dollars in revenue each year.

157. With these concerns in mind, Mr. Campie began independently investigating Gilead's use of Synthetics China as a source of FTC. Mr. Campie's investigation was not within the typical scope of his normal job duties because, as alleged above, Mr. Campie's job function concerned commercial quality assurance (the quality of finished drug product) as opposed to the ongoing quality of API or other drug ingredients.

158. As a result of his investigation, over the course of many months, Mr. Campie discovered a longstanding, systematic and ongoing scheme by Gilead to defraud the Government by selling large quantities of drug products containing contaminated API obtained from Synthetics China that lacked the required Government approval to be marketed.

159. Beginning as early as 2006, Gilead had obtained large quantities of API from SC Plant 202, which it used to manufacture the Affected Drug Products without submitting a PAS that was necessary for Gilead to obtain FDA approval to use Synthetics China as an API manufacturer. [redacted]

160. Gilead initially imported unapproved Chinese-made API into the United States prior to FDA-approval by attributing its manufacture to another of Gilead's CMOs, the South Korean company Yuhan Co Ltd. ("Yuhan"), which had previously been approved by the FDA as an API manufacturing site for Gilead. Gilead falsified its records to misrepresent Yuhan as

producing the API that was actually manufactured by Synthetics China without obtaining required prior FDA-approval. Gilead's internal records reflect that ***for some sixteen months*** Gilead obtained API from Synthetics China that Gilead fraudulently represented as having originated with Yuhan. Gilead used multiple ICNs for the same lots of API that, in reality, originated with the unlicensed, unregistered and non-approved Synthetics China facility. Gilead affixed Yuhan's assigned ICN to lots of the Chinese-made API because the Yuhan ICN was coded to falsely represent the product's suitability for commercial sale in the United States.

161. [redacted]

162. Gilead did not submit a PAS for Synthetics China until October 20, 2008. Gilead submitted misleading statements and falsified data and testing results in its PAS, however. As evidence that the Chinese site was capable of producing API of an acceptable quality, Gilead stated that it had successfully manufactured three commercial-scale batches of API from the new Chinese site. Gilead's application cited and relied on the test results from the manufacturing activity and associated data to conclude both that API manufactured at this new site was equivalent to API manufactured elsewhere, and that Gilead's use of this new site would not adversely impact the safety and efficacy of its drugs.

163. Gilead's actual testing and data from these test batches indicated that nothing was further from the truth, however. Two of the three test batches in fact had failed testing prior to their inclusion in Gilead's PAS filing.

164. The first of the batches, lot number 1071201, contained residual solvent levels in excess of established limits, and testing confirmed the presence of other impurities in excess of

established limits. Gilead's internal documentation reveals that Gilead conducted redundant impurity testing on this batch—i.e. ran the same tests multiple times—in an attempt to re-test the batch into compliance by trying to generate a range of results from which they could cherry-pick passable results. After numerous rounds of re-testing between 2007 and 2009 (all of which failed to yield any passable results), Gilead gave up and concluded that the batch had indeed failed testing.

165. The second test batch, lot number 1080904, contained microbial contamination. Gilead's analysis revealed that the batch contained two different micro-organisms, including *bacillus cereus*, which can be potentially fatal in an immune-compromised population (which is of particular concern here, given that this API was destined to be incorporated into drugs for patients infected with HIV). Testing confirmed that this second batch was contaminated with mold and yeast above established limits. The batch was also contaminated with heavy metals: arsenic, chromium, and nickel. In addition, this batch failed stability testing—indicating that it did not retain its strength, quality, purity, and/or potency during its shelf-life. Gilead did not report and/or actively concealed this from the FDA, and thus, fraudulently attempted to gain approval for the use of a Chinese manufacturing site that was demonstrably unable to qualify as an FDA-approved manufacturing site; produced API that was contaminated; was not equivalent to API sourced elsewhere; and was of substandard strength, quality, purity, potency safety and/or efficaciousness.

166. Recognizing that it had submitted false statements to the FDA in its PAS and that the data and testing on which Gilead relied did not support the company's assertion that the Chinese site was capable of manufacturing safe and efficacious drug product, Gilead quickly secured two new batches of API from the Chinese site in yet another attempt to test into compliance. Gilead then amended its PAS on April 24, 2009, to remove the data and testing from the two failing test batches and insert the substitutes in their place. Data and testing from the third initial test batch, lot number 1080905 (the sole batch that yielded passable test results), continued to be relied upon in the amended PAS.

167. Gilead never acknowledged or notified the FDA about its material omissions, false statements, contamination and adulteration problems, and failing test results and data. The inspection and data review associated with the audit of Synthetics China was based on untruthful facts and misleading data.

168. Gilead's amended PAS was eventually approved (approval consisting of PAS filing, site inspection, gaining a (site) establishment registration number and NDC number assignment) by the FDA in early 2010. Had the FDA known of Gilead's material omissions, false statements, contamination and adulteration problems, and failing test results and data, the FDA could not have approved the company's PAS and hence could not have approved Synthetics China as a registered manufacturing site. Nor could the Government have allowed Gilead to participate in the Government Payment Programs with respect to adulterated drug products containing the contaminated API.

169. What happened with the two batches of contaminated and adulterated Chinese-made API that Gilead excised from its PAS? Gilead subsequently incorporated this contaminated and adulterated API into finished drug product, which the company then released for commercial sale. More disturbingly, Gilead then dismissed the numerous contamination and adulteration problems it identified in the two failing test batches by falsely documenting that the contamination and adulteration issues were somehow unique to these lots—rather than an indication of systemic problems with the manufacture of API sourced on the cheap from a new, uninspected, and unapproved Chinese facility. To avoid interrupting the ongoing commercial-scale manufacture of API, Gilead instructed Synthetics China to continue its operations and resolved only to "monitor metal levels" and "monitor arsenic levels" of the Chinese-made API.

3. Gilead's Use of Contaminated FTC Sourced from China

170. As alleged above, when a pharmaceutical company seeks to begin using a new manufacturing site via a PAS application, it is prohibited by law from distributing drug product manufactured at the new facility prior to obtaining the FDA's approval for the change. 21 U.S.C. §356a(c); 21 C.F.R. § 314.70(b)(3). Before Gilead could lawfully distribute any drug

products incorporating API manufactured by Synthetics China, therefore, it had to submit a PAS and obtain Government approval from the Secretary of HHS for "distribution of the drug as so made." 21 U.S.C. § 356a(b). The Affected Drug Products, which were distributed into commerce before the FDA approved Gilead's PAS for Synthetics China, were ***not*** "approved for safety and effectiveness" as a prescription drug under the FDCA and, as a consequence, did not satisfy the conditions for payment under the Government Payment Programs.

171. On Gilead's instructions, however, Synthetics China had begun manufacturing API for Gilead on a commercial scale in early-2008, and Gilead began covertly distributing unapproved Chinese-made API as early as two years before receiving regulatory approval. Gilead did this with full knowledge of its illegality for, as Gilead publically acknowledged in its 2009 10-K filing:

> In addition to obtaining FDA approval for each drug, we obtain FDA approval of the manufacturing facilities for any drug we sell, including those of companies who manufacture our drugs for us. All of these facilities are subject to periodic inspections by the FDA. The FDA must also approve foreign establishments that manufacture products to be sold in the United States and these facilities are subject to periodic regulatory inspection.

Gilead Sciences, Inc., 2009 Form 10-K Annual Report.

172. Between September 2008 and August 2009, Synthetics China had manufactured [redacted] commercial-scale batches—representing tons of API—which Gilead incorporated into finished drug product and released for commercial sale in violation of the FDCA and the regulations promulgated thereunder.

173. Gilead actively concealed from the Government the fact that it had sourced unapproved API from this foreign, unregistered and uninspected manufacturing facility. As an example, lot number 1080905 (the third of the initial test batches) was released for commercial use on May 14, 2009 - and distributed for commercial sale. Gilead concealed its end-run around the FDA-CMS approval process through more fraud.

174. As the first step in the scheme, Gilead transferred the adulterated API from Synthetics China to Gilead's Canadian subsidiary, Gilead Alberta. Because Synthetics China

was an unregistered, unapproved facility it lacked the site registration and NDC code required at the time for API destined for commercial sale. Gilead therefore arranged to ship the adulterated Synthetics China API to Gilead, Alberta using shipping labels and/or accompanied by paperwork with an Investigational New Drug ("IND") designation. These records were false because Gilead was actually transferring large quantities of the adulterated Synthetics China API to Gilead, Alberta for the express purpose of concealing its true origin at the unregistered Chinese facility and ultimately incorporating the Chinese API into the finished Affected Drug Products for commercial sale.

175. After the Chinese API arrived at the Gilead, Alberta facility, Gilead removed the "IND" label and prepared replacement Gilead COAs and generated MSN forms designating the API as "Released" for "Human Use (Commercial)." Gilead then shipped the relabeled Chinese API, using the Gilead COAs and MSNs containing false certifications, to Patheon, a Canadian CMO, which incorporated the API into the Affected Drug Products for import into the United States and commercial sale. (Gilead later used its own facility in Cork, Ireland to also process the contaminated API into Truvada and Atripla tablets.)

176. Once Patheon manufactured the Chinese API into bulk tablets, Gilead would prepare and issue a new MSN approving payment to Patheon and designating the Affected Drug Products as "Released." The finished Affected Drug Products were generally shipped in drums to Gilead in San Dimas, California, where the tablets were packaged into commercial bottles. Gilead then prepared a falsified COA to accompany the commercial release of the Affected Drug Products into interstate commerce.

177. The initial run of the [redacted] Chinese-made lots of API was released during September of 2008 to August of 2009. Despite evidence of contamination and adulteration problems, the vast majority of these lots were incorporated into batches of finished drug product and distributed for commercial sale. Three of these lots were rejected "for reprocessing" because of unspecified impurities, only to be re-introduced into commercial sale

later. Another lot was relegated for use in a clinical study because testing confirmed out-of-trend density results and contamination with 1-propanol and assay.

178. An additional [redacted] were produced at Synthetics China between September 2009 and August 2010. Yet as of March 2010, SC Plant 202 still had not received the required Establishment Identification Number and therefore was still not registered with the FDA. Gilead also identified other impurities in this SC Plant 202 API, confirming among other things the presence of a [redacted] in numerous of these lots manufactured by Synthetics China.

179. Despite the fact that the foregoing impurities exceeded identification and reporting thresholds—guiding industry standards promulgated by the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use ("ICH"), an international organization comprised of both pharmaceutical regulatory authorities from Europe, Japan, and the United States, and experts from the pharmaceutical industry itself—Gilead instructed laboratory personnel to ignore these impurity profiles and omit them from any subsequent reports. The company also incorporated this directive into its standard test methods. As a result, Gilead consciously ignored these impurity issues and concealed their existence from the Government.

4. Synthetics China expands production and new contamination and adulteration problems ensue

180. Gilead sought to quickly expand its use of the Chinese CMO and the inexpensive API it produced. Accordingly, in August 2010 validation batches were produced and by December of 2010, Synthetics China began operating a new, [redacted] manufacturing facility (SC Plant 203) that was dedicated solely to manufacturing API for Gilead. As alleged above, this facility was known as "Plant 203." The new facility immediately began [redacted] commercial operations manufacturing Gilead API without any apparent regulatory notification or approval -- despite the fact that Gilead was changing the scale of the API manufacturing and transitioning to this new, uninspected and unapproved facility.

181. Instead, [redacted] manufactured three process validation batches of API manufactured at SC Plant 203 on which the company conducted tests and collected data. Gilead issued a validation report supporting the use of FTC API manufactured at SC Plant 203, [redacted]

182. As before, false COAs were generated to make the batches appear to meet specifications – however, these test batches were grossly contaminated and adulterated. Two of the validation lots contained multiple contaminates, including, but not limited to colored glass, cement, and fibrous building materials. The size of many of these contaminates was significant—Gilead measured and confirmed that the largest single shard of foreign matter found was 7.8% the size of a finished Truvada tablet or 19.5% the size of a finished Emtriva capsule (by weight). The third lot was contaminated by "brown paper strips" and "pinkish-orange particles," the latter of which was described only as "unidentified organic material."

183. Gilead learned that Plant 203 was manufacturing contaminated API by no later than November of 2011. By this time, however, large quantities of API from Plant 203 had already been incorporated into finished Gilead drug product and distributed for commercial sale. This discovery created an internal panic, and [redacted] This new round of tests confirmed the gross contamination of API manufactured at SC Plant 203, and, while Gilead documented and photographed its findings, it did not report them to the Government.

184. The amount of Chinese-made API from SC Plant 203 that was impacted by this contamination and adulteration problem is significant. By the time Gilead discovered the contamination problems in SC Plant 203, nine batches of API from that site had already been incorporated into finished drug product (including process validation batches of Atripla and

Truvada) and commercially sold. Each of these batches represents approximately [redacted] bottles of finished drug product yielding total sales in excess of $100 million.

185. Gilead was still left with [redacted] of contaminated and adulterated API on hand from SC Plant 203 worth in excess of $2 billion. Contaminated product (API / DS) is not allowed to be reprocessed or reworked – but rather destroyed. However, Gilead did not destroy this material. Instead, Gilead shipped the contaminated API from Patheon to Gilead Alberta in Canada, where Gilead Alberta proceeded to sift out foreign contaminates from the [redacted] of Chinese-made API, one drum at a time. The results from this operation are dramatic, as Gilead documented the removal of [redacted] of contaminates and foreign material from the adulterated API.

186. Gilead sieved the Chinese-made API in an attempt to remove the larger foreign contaminates—documenting and photographing what it discovered during the process. In the FTC manufactured by SC Plant 203 (and subsequently incorporated into drugs that were sold and ultimately ingested by patients), Gilead clandestinely catalogued what it classified as "glass-like shards"; "black, rubber-like, particles"; "plastic-like particles"; "small stone or pebble-like particles"; and "metal shards."

187. After picking out as much through sieving as it could, Gilead assigned a new ICN to the lots of adulterated and Chinese-made API. Gilead removed the ICN assigned to Synthetics China (ICN-056) (and thus any association with SC Plant 203 and its serious contamination problems), [redacted]

[redacted]

188. Notably, this document, which captured the activity and rationale for conducting the exercise, was not approved until July of 2012, and was generated only ***after*** an FDA inspection occurred during which the FDA observed the lack of recall actions for the batches that had been released into commerce. All the while Gilead continued to incorporate these batches of adulterated Chinese-made API into finished drug product (including the Affected Drug Products) and distribute them for commercial sale. In response to the FDA Warning Letter, Gilead asserted that it would be better if patients took contaminated drugs than no drugs at all.

189. Despite being plagued with the continuing contaminated and adulterated API manufactured by Synthetics China, Gilead did not cease using Synthetics China as a CMO – instead finally declaring Synthetics China "inactive" in October 2011. Gilead nonetheless continues to incorporate Synthetics China-made API into its finished drug products. As a result, there have been two recalls of those finished drug products to date: (1) on February 19, 2014 three lots of Atripla due to contamination with red silicone particulates, and (2) in October 2014 one lot of Truvada due to contamination with the same red silicone particulates. In addressing the Atripla recall, Gilead publically attributed the contamination to its use of a third-party manufacturer in China, i.e., Synthetics China.

5. Specific Examples of Gilead's False Certifications, Statements and Records

190. As explained above, before releasing a drug product into interstate commerce, the Government requires Gilead to make certain basic compliance certifications relating to the

[16] [redacted]

source, quality, and conformance to federal regulations that govern the drug product and its manufacturing practices and processes. Also as explained above, compliance with the FDCA and the regulations promulgated thereunder is a prerequisite for Government approval to place the drug product into interstate commerce under the FDCA and thus for participation in and payment under the Government Payments Programs.

a. PAS Certifications

191. Requesting regulatory approval of a major change in a drug's manufacturing process via a PAS requires the submission of a completed Form 356h. [redacted] This form contains the following express compliance certification:

> **CERTIFICATION**
>
> I agree to update this application with new safety information about the product that may reasonably affect the statement of contraindications, warnings, precautions, or adverse reactions in the draft labeling. I agree to submit safety update reports as provided for by regulation or as requested by FDA. If this application is approved, I agree to comply with all applicable laws and regulations that apply to approved applications, including, but not limited to, the following:
>
> 1. Good manufacturing practice regulations in 21 CFR Parts 210, 211 or applicable regulations, Parts 606, and/or 820.
> 2. Biological establishment standards in 21 CFR Part 600.
> 3. Labeling regulations in 21 CFR Parts 201, 606, 610, 660, and/or 809.
> 4. In the case of a prescription drug or biological product, prescription drug advertising regulations in 21 CFR Part 202.
> 5. Regulations on making changes in application in FD&C Act section 506A, 21 CFR 314.71, 314.72, 314.97, 314.99, and 601.12.
> 6. Regulations on Reports in 21 CFR 314.80, 314.81, 600.80, and 600.81.
> 7. Local, state, and Federal environmental impact laws.
>
> . . .
>
> The data and information in this submission have been reviewed and, to the best of my knowledge, are certified to be true and accurate.

Warning: A willfully false statement is a criminal offense, U.S. Code, title 18, section 1001.

192. Because of the illegal release and distribution of contaminated and adulterated drug product from an uninspected and unapproved Chinese CMO, Gilead made false statements by making these certifications and by completing, signing, and submitting these two forms. Gilead made these false statements to fraudulently obtain FDA approval of these manufacturing sites and to obtain payment for drug product produced there from the Government and the States under the Government Payments Programs.

b. COA and MSN Certifications

193. For each batch of API produced by Synthetics China, the Chinese CMO generated a COA that certifies the batch is within approved specifications. [redacted]

194. [redacted]

195. [redacted]

196. The foregoing COAs and MSN generated for the batches of API manufactured at Synthetics China contained false certifications of compliance with the FDCA and the cGMPregulations promulgated thereunder.

197. Because of the illegal release and distribution of contaminated and adulterated drug product from API sourced from an uninspected and unapproved Chinese CMO, Gilead made false statements by making these certifications. Gilead made these false statements to fraudulently obtain Governmental approval of these manufacturing sites and to obtain payment from the Government and the States under the Governmental Benefits Programs for drug product produced there.

c. State-issued distribution licenses

198. Most States require a valid state-issued license in order to distribute prescription drugs within that State. A State's application process typically requires the applicant to submit a signed certification. Examples of these certifications include:

199. Arkansas:

> I swear, or affirm that all statements made herein and on the attached forms are true and correct. All of the provisions of Arkansas laws and regulations related to the wholesale distribution of drugs into Arkansas will be faithfully observed during the period any permit issued may be in force and effect.
>
> This business . . . complies with all applicable federal, state and local laws and regulations . . . .

Arkansas State Board of Pharmacy, Application for Wholesale Distributor of Prescription (Legend) Drugs Permit. Gilead has completed this application and obtained a license from the state of Arkansas to distribute prescription drugs within the state. Because of the illegal release and distribution of contaminated and adulterated drug product from an uninspected and unapproved Chinese CMO, Gilead made false statements by making this certification.

200. Louisiana:

> Application Certification: I hereby certify . . . by my signature below, the applicant [] will operate the facility in a manner prescribed by federal, state, and local laws and all rules promulgated by the Board . . . .

Louisiana Board of Wholesale Drug Distributors, Form 201405-1, Application for License Wholesale Distributor of Legend Drugs or Devices. Gilead has completed this application and obtained a license from the state of Louisiana to distribute prescription drugs within the state. Because of the illegal release and distribution of contaminated and adulterated drug product from an uninspected and unapproved Chinese CMO, Gilead made false statements by making this certification.

201. Michigan:

> **MANUFACTURING PRACTICE**
>
> Do you maintain the building, operate the equipment, and administer the controls, records and methods used for, and in connection with, the manufacturing, processing, packing, labeling, holding, and distributing of all prescription drugs in conformity with current good manufacturing practices pursuant to the criteria set forth in the provisions of 21 C.F.R. 211.1 to 211.208.

Michigan Department of Licensing and Regulatory Affairs; form LARA/LPH-811. Gilead has completed this application and obtained a license from the state of Michigan to distribute prescription drugs within the state. Because of the illegal release and distribution of contaminated and adulterated drug product from an uninspected and unapproved Chinese CMO, Gilead made false statements by making this certification.

202. Montana:

> **DECLARATION**
>
> . . .
> I have read and will abide by the current licensure statutes and rules of the State of Montana governing the profession. I will abide by the current laws and rules that govern my practice.

Montana Board of Pharmacy, Wholesale Drug Distributor form. Gilead has completed this application and obtained a license from the state of Montana to distribute prescription drugs within the state. Because of the illegal release and distribution of contaminated and adulterated drug product from an uninspected and unapproved Chinese CMO, Gilead made false statements by making this certification.

203. Texas:

> VERIFICATION: . . . I FURTHER CERTIFY THAT I HAVE READ AND UNDERSTAND CHAPTER 431 OF THE HEALTH & SAFETY CODE, THE APPLICABLE PROVISIONS OF 25 TEXAS ADMINISTRATIVE CODE, CHAPTER 229,[17] AND AGREE TO ABIDE BY THEM.

Texas Department of State Health Services, RLU, Food & Drug Licensing, form EF23-13016. Gilead has completed this application and obtained a license from the state of Texas to distribute prescription drugs within the state. Because of the illegal release and distribution of contaminated and adulterated drug product from an uninspected and unapproved Chinese CMO, Gilead made false statements by making this certification.

G. GILEAD'S CORPORATE CULTURE OF NON-COMPLIANCE

204. A person acts "knowingly" under the FCA if that person "(i) has actual knowledge of the information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (iii) acts in reckless disregard of the truth or falsity of the information." 31 U.S.C. § 3729(b)(1) (A).

205. Gilead's generation of the false statements, records and certifications described above was done in "knowingly" within the meaning of the FCA, and in conscious awareness of

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[17] 25 Tex. Admin. Code § 229.429 provides in pertinent part that:

> (a) . . . All persons engaged in the wholesale distribution of prescription drugs must comply with the applicable minimum standards in this section, in addition to the statutory requirements contained in the Texas Food, Drug, and Cosmetic Act, Health and Safety Code, Chapter 431 [] and those requirements in §229.420 of this title . . . .
>
> . . .
>
> (c) Manufacturers of prescription drug products shall be in compliance with the applicable requirements in 21 CFR, Part 210, titled "Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding of Drugs"; 21 CFR, Part 211, titled "Current Good Manufacturing Practice for Finished Pharmaceuticals; General" . . . . The regulations in these parts govern the methods used in, and the facilities or controls used for, the manufacture, processing, packing, or holding of a drug to assure that each drug meets the requirements of the Federal Act as to safety, and has the identity and strength and meets the quality and purity characteristics that it purports or is represented to possess.

the fact that the Government could not under the Government Payment Programs pay for drug products manufactured with contaminated API from an unregistered foreign source in non-compliance with the FDCA. Gilead's actions were not mere oversights or innocent mistakes; the actions were deliberately taken and covered up to avoid financial loss to Gilead were it not to use the enormous amount of FTC Gilead had obtained from SC Plant 202 and SC Plant 203.

206. Gilead's knowing misconduct is consistent with what Mr. Campie discovered to be Gilead's shocking attitude regarding the concealment of API contamination from the Government. [redacted] Mr. Campie was alarmed to read this, as he knew from his training and experience that the presence of these contaminates rendered the produce adulterated under FDCA law and regulations.

207. A few days after Mr. Campie was provided with the report, he was asked to participate in an internal discussion regarding the allowable levels of metal in a Gilead drug product. During this discussion, Mr. Campie disagreed with the suggestions of the report's author, Tammis Matzinger, that such contamination should be tolerated, and firmly stated that the presence of foreign metal in a finished drug product is unacceptable and would cause the drug product to be "adulterated' under the FDCA.

208. The report was no aberration because [redacted] These SOPs were initially adopted in January 2001, prior to Mr. Campie's employment; Gilead management reviewed and reaffirmed this policy several times during the course of Relators' employment. To Relators' knowledge, these SOPs are still in force and followed at Gilead.

209. Shortly after he began his employment with Gilead, Mr. Campie was tasked with chairing an internal Quality Council, which was staffed with Gilead employees of various quality functions and created to discuss and resolve quality-related issues. The Council had regular monthly meetings, and additionally met on an ad hoc basis as needed. In one Quality Council meeting in late 2006 or early 2007, Mr. Campie voiced opposition to a recommendation that the company close out a complaint in which metal shards had been found in a drug tablet without investigating or any further action. Mr. Campie voiced his concerns and stated that product contamination and adulteration was a serious problem at Gilead. News of the meeting and of Mr. Campie's comments traveled quickly, and a Senior Director in Gilead's Legal Department approached Mr. Campie in his office later that same day to ominously warn him that "discussing those subjects will severely limit your career in the company." Mr. Campie was removed as head of the Quality Council in mid-2008.

H. GOVERNMENT PAYMENT FOR THE AFFECTED DRUG PRODUCTS

210. Gilead's false statements, certifications and records described above caused the Government to make payments for Affected Drug Products under the Government Payment Programs.

211. With complete access to Gilead's records, for example, one can trace the contaminated API sourced from SC Plant 202 China and SC Plant 203 from the original API acquired by Gilead through the batches of Affected Drug Product released by Gilead. [redacted]

212. With complete access to Gilead's records, one can also match the Affected Drug Products commercially released by Gilead and the corresponding claims for payments made to the Government and the States under the Government Payment Programs.

213. Moreover, payment by the Government and the States for the Affected Drug Product can also be demonstrated through records maintained by the Government and the

States, as illustrated by the OIG review of such data referenced in Paragraph 21 above. For example, when a pharmacy dispenses drugs to a Medicare beneficiary under Medicare Part D, it submits an electronic claim to the beneficiary's Part D plan and receives reimbursement from the plan sponsor for the costs not paid by the beneficiary. The Part D plan sponsor then notifies CMS that a drug has been purchased and dispensed through a document called a Prescription Drug Event ("PDE") record, which includes the name of the drug product and the amount paid to the pharmacy. The PDE is an electronically created document that includes at least thirty-seven fields of information about a specific drug transaction. CMS uses the information in the PDE at the end of the payment year to reconcile its advance payments to the sponsor with actual costs the plan sponsor incurred.

214. As another example, with respect to the Medicaid program the Government secures and maintains state drug utilization statistics, on a per drug and per prescription basis, from which payments for the Affected Drug Products can be similarly ascertained. Two examples of the level of detail of state utilization records showing payments for Gilead's drug products are attached as Exhibits 9 and 10.[18]

215. The Government also maintains records reflecting its direct payment for Gilead drug products, including the Affected Drug Products, under the PEPFAR Program. An example of the level of detail of PEPFAR acquisition records showing payments for Gilead's drug products on a country by country basis is attached as Exhibit 11.[19]

216. In sum, there are ample "reasonable indicia" that the alleged false claims for payment of the Affected Drug Products were in fact submitted to Government and the States for payment under the Government Payment Programs. *Ebeid v. Lungwitz*, 616 F.3d 993, 999 (9th Cir. 2010).

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[18] http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Medicaid-Drug-Rebate-Program.html

[19] www.pepfar.gov/documents/organization/105842.pdf

RETALIATION AGAINST MR. CAMPIE

217. As explained above, Relators discovered [redacted] of contaminated and adulterated API that had been manufactured at an unregistered and uninspected Chinese CMO and distributed without any valid PAS approved by the FDA; that had not properly been demonstrated to be (and in fact was not) equivalent to FDA-approved API; that was of substandard strength, quality, purity, potency, safety and/or efficaciousness; and that had been used to submit falsified testing, data, and statements to the FDA. Relators further discovered that this contaminated and adulterated API had been covertly and illegally released and distributed for commercial sale into the United States and ultimately paid for by the Government and States under the Government Payment Programs.

218. Under the circumstances alleged above and as alleged in further detail below, Mr. Campie believed in good faith – as would any reasonable employee in the same or similar circumstances – that Gilead was defrauding the Government and the States by knowingly seeking payment for contaminated drugs, first without obtaining required governmental approval and later based on falsified test results, false certifications and falsified PAS documents.

219. Furthermore, Gilead was made aware of Mr. Campie's concerns at several different levels of management, inside and outside the chain of command and, as alleged below, Gilead believed that Mr. Campie was engaged in protected activities and took adverse action against him for that reason.

220. In July 2007, after repeated discussions with both the quality assurance personnel responsible for API oversight and his own product release group, Mr. Campie authored a Notification to Management memo in which he expressed concern over not having access to investigations, deviations and discrepancies with the potential to adversely impact the quality of commercial drug product. Mr. Campie delivered this Notification to Management memo to his manager, Tony Caracciolo. Mr. Campie continued to raise these issues and concerns with his immediate superior on many occasions over the following weeks and months.

At the same time, Mr. Campie becomes increasingly concerned about the integrity of the data being generated to support the release of Gilead drugs.

221. On multiple occasions, including at weekly one on one and senior staff meetings, Mr. Campie discussed the contamination and adulteration problems with the API being used by Gilead and, more particularly, with Gilead's knowing use of falsified data and test results for the express purpose of introducing non-approved and contaminated drugs into commerce. [redacted] Mr. Campie was told that it was "none of his concern" which he reasonably took as a warning to stop raising concerns over Gilead's manufacture and sale of contaminated drugs using API manufactured at unregistered facilities that Gilead was using to cut costs and thereby increase its profits from governmental sales.

222. In late 2008, Mr. Campie was presented with a document (Change Control Implementation Plan or CCIP) authorizing the use of API manufactured by Synthetics China. Mr. Campie, already concerned regarding the quality of the API being used in Gilead drugs, held multiple meetings with both the commercial operations group and the API procurement personnel in an effort to remind and warn the company that drugs containing API sourced from the unregistered, unlicensed and non-approved Synthetics China plant could not be shipped or otherwise distributed into commerce without violating the applicable laws.

223. In January 2009, after exhausting all other avenues, Mr. Campie convened another meeting to once again caution Gilead management that API could not be shipped from a manufacturing site that had never been inspected by the regulatory authorities, had never been registered and had not obtained the required Establishment Identification Number. The meeting, which occurred on January 12, 2009, was called in part because [redacted] David Upchurch, the head of API Manufacturing at Gilead, attended the meeting and, the very next

day, [redacted] -- meaning that Gilead intended to mislabel the API as investigational batches rather than truthfully reflecting that the batches in question were being shipped to Patheon for commercial production. *Id.*

224. Unbeknownst to Mr. Campie at the time, David Upchurch was involved in and knew of Gilead's prior use of Yuhan as a shadow establishment to smuggle into commerce contaminated API that was actually produced at the unregistered, uninspected and unapproved Synthetics China SC Plant 202 during 2006-2008, as alleged in Paragraph 161 above. Mr. Upchurch's involvement and knowledge are reflected in the [redacted]

225. In early Feb 2009, Mr. Campie participated in the review and approval of a Health Canada submission associated with the use of Synthetics China API. During his review, Mr. Campie identified failing and inconsistent test data, which he brought to the attention of Tyler Rodgers (Regulatory Affairs / Canada). Subsequently, Mr. Rodgers [redacted]. In response to his concerns, another Gilead employee suggested that the questionable documents be replaced with Gilead-generated documents, which would falsely identify the source and origin of the contaminated API. During subsequent discussions, Mr. Campie learned that Gilead already had submitted the failing test data to the FDA months earlier in support of a PAS seeking approval for the use of Synthetics China API.

226. Mr. Campie continued to voice strenuous objections to the false representations and omissions being made to the Government concerning the source and lack of purity of the API from Synthetics China and that lack of a truthful, valid and approved PAS. Mr. Campie voiced these concerns to his colleagues, his manager, and to employees at Patheon, the CMO that Gilead was using to produce the contaminated API into bulk tablets. Also in early February

2009, Mr. Campie attempted to challenge the release of Viread tablets which had been badly degraded during the manufacturing process at a CMO in Germany. Ultimately, Mr. Campie's manager ignored his concerns and ordered that the material nevertheless be released and shipped to Gilead's San Dimas facility for packaging and commercial release. The same batches in question were subsequently included in an FDA Warning Letter which Gilead received in September 2010.

227. Although Mr. Campie was supposed to be responsible for commercial quality input on regulatory filings implicating quality or supply issues, Gilead began to selectively circumvent Mr. Campie's review and effectively removed and excluded him from Gilead's regulatory review process. Within weeks after Mr. Campie voiced objections to the continued unauthorized use of Synthetics China as an API supplier, Gilead management bypassed Mr. Campie completely on the review of the Synthetics China PAS submissions. Given the timing of this exclusionary conduct, management's disdainful disregard of Mr. Campie's prior complaints and the fact that Mr. Campie's job responsibilities as head of commercial QA included the review of the regulatory submissions to the FDA, Mr. Campie reasonably concluded that Gilead was retaliating against him to avoid further scrutiny of its ongoing fraudulent conduct with regard to the Synthetics China sourced API.

228. When Mr. Campie explicitly complained that Gilead was violating FDA regulations in order to sell its drugs to the Government and States notwithstanding their lack of compliance with the FDCA and cGMP, he was castigated by Senior Director of Commercial Manufacturing Wayne DeJong, who told him that he was "the major obstacle in getting material into commercial production" and that he should go along with the release and sale of contaminated product "for the good of Gilead."

229. Also in February of 2009, Mr. Campie had an annual performance review with Gilead's Senior Vice President of Manufacturing and Operations, Tony Caracciolo. Mr. Caracciolo stated during this performance review that although Mr. Campie had displayed his "extensive knowledge," he was "not effective in influencing peers" and should therefore start

looking for employment elsewhere. Mr. Campie reasonably understood Mr. Caracciolo's comments as a treat that Gilead intended to terminate him because of the numerous times he had objected to and attempted to rectify Gilead's contamination and adulteration problems and related deceptive practices. In response, Mr. Campie reiterated the concerns he had repeatedly raised about Gilead's non-compliant practices, including the contamination and adulteration problems, falsified data issues at Synthetics China and resulting fraudulent sales of contaminated and misbranded drugs, including sales to the Government. Mr. Campie reasonably concluded that Gilead was planning to terminate or take other adverse action against him because of his efforts to put a halt to Gilead's fraudulent practices vis-a-vis the Government.

230. Shortly thereafter, on March 19, 2009, Mr. Campie arranged to meet with the company's Chief Compliance Officer, Ron Branning, to discuss the falsified data and test results in the Synthetics China PAS. During this conversation, Mr. Campie discussed issues involving data integrity, the generation of false and redundant COAs designed to conceal Gilead's wrongful conduct and its falsification and attempted eradication of failing validation test data. Mr. Campie also invited Ms. Deborah Pagano (former FDA Inspector) into the discussion (via telephone from Gilead Ireland) where she echoed similar concerns. At the conclusion of the meeting, Mr. Campie was asked "what he expected Mr. Branning to do?" Mr. Campie made clear that he expected Gilead to stop its deceptive practices and threatened to inform the FDA if Gilead continued its fraudulent conduct.

231. In early April of 2009, Mr. Campie received an email from Brad Wigglesworth (GM of the Gilead San Dimas facility) that stated: "Well, at least I won't have to put up with you much longer." This comment was made within the context of Mr. Campie's assuming responsibility for the Gilead Customer Complaint call center. Mr. Campie reasonably viewed this comment as an indication that senior Gilead management had informed others as to their intention to take adverse action against him because he had complained about Gilead's fraudulent practices.

232. On April 17th of 2009, Mr. Campie learned that Gilead was preparing to release and distribute in the United States the commercial drug Letairis using ambrisentan API once again manufactured at an unregistered and non-approved production facility. Gilead had sought permission to begin using its Canadian facility to manufacture ambrisentan, the active ingredient in the drug Letairis. While this request for regulatory approval to add a new manufacturing site should have been accomplished through a PAS, the company instead, submitted its request through a Changes Being Effected ("CBE") notification, which is reserved for minor changes in the production process. In the interim, Gilead had made multiple batches of the drug product and had shipped them to its San Dimas facility for commercial distribution. Although he was formally a quality review/approver for such types of changes, Mr. Campie was not made aware of the regulatory submission since the company was via a "forced workflow" re-routing the documents around him. Mr. Campie only learned of what transpired when the FDA issued a non-approval letter for Gilead's CBE notification.

233. By that time, however, Gilead had once again already manufactured multiple batches of ambrisentan at its Canadian facility, incorporated the API into finished product at Patheon and had staged the batches for release, pending sales orders, in the Gilead San Dimas, CA facility. When Mr. Campie learned about Gilead's plan to distribute non-approved drugs, he instructed that the batches be removed from the company's supply chain and placed into quarantine until Gilead received Government approval to place them into the stream of commerce, in accordance with FDA regulations, 21 C.F.R. § 314.70. Notably, Gilead had earlier stated in a 2007 SEC filing that the unregistered facility was the sole manufacturer of the API.

234. An hour after Mr. Campie had ordered the quarantine, Mr. Caracciolo called Mr. Campie and one of his subordinates who had assisted him into Mr. Caracciolo's office. Mr. Caracciolo told Mr. Campie that initiating quarantine was not in his job description and stated in no uncertain terms that Mr. Campie had no authority to order one. He then continued to state: "If you guys can't protect product supply, you are of very little use to me." The batches of

finished product using the unapproved API were then released back into Gilead's supply chain, and incorporated into Gilead drug products ultimately released for commercial sale in violation of the FDCA and the regulations promulgated thereunder, and for which Gilead received payment from the Government and the States under the Government Payment Programs.

235. The following week, privately acknowledging that the data submitted in support for Synthetics China FTC API had been misrepresented and fearful that Mr. Campie would keep to his promise of informing the proper authorities, Gilead decided to submit an amendment to the Synthetics China PAS filed in October 2008. Gilead submitted the amended filing to the FDA on April 24, 2009. The FDA approved the amended PAS to add Synthetics China API to the Gilead Truvada drug NDA on May 6, 2009.

236. Gilead management was well aware that Mr. Campie's actions were protected activity under the FCA and related laws. Other Gilead employees were simultaneously voicing concerns echoing Mr. Campie's during the same timeframe. For example, on April 16, 2009, a Gilead co-worker named Sanjay Sehgal sent an email to Mr. Campie's manager, Tony Caracciolo, expressly warning that the use of non-approved ambrisentan in the Letaris products manufactured at Gilead, Alberta "is a concern as it would be classified [by the FDA] as unapproved product" and Gilead therefore should self-report to the FDA.

237. As Gilead management continued to threaten adverse action against him, Mr. Campie continued to speak with other employees within Gilead who were encountering the same threatening conduct by Gilead after attempting to address regulatory violations resulting in false claims under the Government Payment Programs. In May of 2009, one such employee wrote to Mr. Campie that "every time we point out issues related to the quality of our product we are perceived like the 'enemy of the state,' that "[t]he company is withholding relevant and pertinent information from the FDA and other information [submitted to the regulatory authorities] is manipulated so no action is taken" to correct the fraudulent conduct. The employee went on to observe that Mr. Campie was "trying your best to correct this but you are not getting the support of the Senior management" and predicted that Gilead was likely to

fabricate reasons to fire her. Mr. Campie was requested to layoff the employee in early June 2009.

238. Then, on June 30, 2009, Mr. Campie was called into a meeting and told he would be terminated, effective July of 2009. The phony rationale given by Gilead was that Mr. Campie's "heart wasn't in the job anymore." During this meeting, Mr. Campie once again tried to raise the topic of Gilead's noncompliant practices, including the problems at Synthetics China and the ongoing adulteration of an Anti-HIV drug for infants with Teflon from a piece of manufacturing equipment. In response, he was told, "Who are you working for—the company or the FDA?" Mr. Campie subsequently stated that he was going to go to the proper authorities over the matters he had observed. To which, Mr. Caracciolo warned Mr. Campie that "It's a very small industry and that "he would do what he had to do to protect the company" (as a Gilead officer).

239. Even so, Mr. Campie refused to drop his concerns, and on July 15, 2009, he met with representatives from Gilead's Legal department.

240. Gilead then asked Mr. Campie to sign a severance agreement in which he would agree not to initiate a FCA claims against Gilead, confirming Gilead's awareness that Mr. Campie reasonably believed -- and had communicated to Gilead his belief -- that Gilead was committing a fraud against the Government. Mr. Campie refused.

241. Based on the foregoing circumstances and the timing of the events that transpired between January of 2009 and Mr. Campie's termination months thereafter, Mr. Campie firmly believes that he was ostracized, demoted and ultimately terminated because of his investigation into and persistent objections to Gilead's use of the contaminated API from a sources that was not approved by the Government to make drug products that were not approved by the Government, which were plainly leading to the submission of false claims for payment of the Affected Drug Product under the Government Payment Programs.

242. Mr. Campie was subjected to these adverse employment actions, including specifically his termination on June 30, 2009, because of his persistent efforts to investigate matters that both he and Gilead knew were reasonably calculated to lead to viable FCA claims.

243. Since his termination, Mr. Campie has, as Mr. Caracciolo warned, had difficulty finding comparable employment in the industry.

CAUSES OF ACTION

COUNT ONE
VIOLATION OF 31 U.S.C. § 3729(a)(1)(A)

244. Relators incorporate the allegations contained herein and hereby reallege them as set forth fully above.

245. The FCA, 31 U.S.C. § 3729(a)(1)(A) provides that any person who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval . . . is liable to the United States Government for a civil penalty of not less than $5,000 and not more than $10,000, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990 . . . plus 3 times the amount of damages which the Government sustains because of the act of that person."

246. In performing the acts described herein, Gilead through their own acts or through the acts of their officers, knowingly and/or recklessly presented, or caused to be presented, false or fraudulent claims for payment or approval to officers, employees, or agents of the United States and the States under the Government Payment Programs in violation of 31 U.S.C. § 3729(a)(1)(A). Gilead knew that these claims for payment or approval were false, fraudulent, or fictitious, or acted at least in reckless disregard for whether the claims were true or false.

247. Based on the facts alleged above, Plaintiffs assert Gilead's liability under a factually false theory, an express certification theory, an implied certification theory and a promissory fraud theory, and specifically assert:

- Gilead fraudulently represented that the Affected Drug Products satisfied the conditions of participation in the Government Payment Programs through materially false statements and certifications in its PAS filings, COAs, MSNs, shipment documents and falsified test results.

- Gilead knowingly submitted false claims for payment under the Government Direct Pay Programs through express or implied certifications that the Affected Drug Products were approved for safety and effectiveness by the FDA when, in fact, the FDA had not approved any PAS for the Synthetics China facility when the Affected Drug Products were distributed, the PAS submitted by Gilead for Synthetics China contained false certifications and falsified test results and the Affected Drug Products were adulterated;

- Gilead knowingly caused others to submit false claims for payment under the Government Reimbursement Programs through express or implied certifications that the Affected Drug Products were approved for safety and effectiveness by the FDA when, in fact, the FDA had not approved any PAS for the Synthetics China facility when the Affected Drug Products were distributed, the PAS submitted by Gilead for Synthetics China contained false certifications and falsified test results and the Affected Drug Products were adulterated.

248. Each claim presented or caused to be presented for reimbursement under the Government Payments Programs for the Affected Drug Product represents a false or fraudulent claim for payment.

249. Gilead's false representations and omissions were material to the decision of the Government and the States to pay for the Affected Drug Products.

250. As a result of Gilead's conduct, the Government and the States have paid false claims in an amount to be proven at trial.

COUNT TWO

VIOLATION OF 31 U.S.C. § 3729(a)(1)(B)

251. Relators incorporate the allegations contained herein and hereby reallege them as set forth fully above.

252. The FCA, 31 U.S.C. § 3729(a)(1)(B), provides that any person "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim … is liable to the United States Government for a civil penalty of not less than $5,000 and not more than $10,000, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990 . . . plus 3 times the amount of damages which the Government sustains because of the act of that person."

253. By virtue of the acts described above, Gilead knowingly made, used and/or caused to be made or used, false or fraudulent records or statements material to the payment of false or fraudulent claims under the Government Payment Programs within the meaning of 31 U.S.C. § 3729(a)(1)(B).

254. Based on the facts alleged above, Plaintiffs assert Gilead's liability under a factually false theory, an express certification theory, an implied certification theory and a promissory fraud theory and specifically assert that Gilead knowingly made, used and/or caused others to make or use false records or statements that were material to the false or fraudulent payment of claims under the Government Payment Programs by preparing and using false PSAs, false COAs, false MSNs, false shipping documents and falsified test results.

255. Each claim presented or caused to be presented for reimbursement under the Government Payments Programs for the Affected Drug Products represents a false or fraudulent claim for payment.

256. Gilead's false records and statements were material to the decision of the Government and the States to pay for the Affected Drug Products.

257. As a result of Gilead's conduct, the Government and the States have paid false claims in an amount to be proven at trial.

COUNT THREE

VIOLATION OF THE ARKANSAS MEDICAID FALSE CLAIMS ACT
Ark. Code Ann. § 20-77-902

258. Relators incorporate the allegations contained herein and hereby reallege them as set forth fully above.

259. Ark. Code Ann. § 20-77-902 provides liability for any person who:

(1) Knowingly makes or causes to be made any false statement or representation of a material fact in any application for any benefit or payment under the Arkansas Medicaid program;

(2) At any time knowingly makes or causes to be made any false statement or representation of a material fact for use in determining rights to a benefit or payment; or

(3) Having knowledge of the occurrence of any event affecting his or her initial or continued right to any benefit or payment or the initial or continued right to any benefit or payment of any other individual in whose behalf he or she has applied for or is receiving a benefit or payment knowingly conceals or fails to disclose that event with an intent fraudulently to secure the benefit or payment either in a greater amount or quantity than is due or when no benefit or payment is authorized.

260. Gilead violated Ark. Code Ann. § 20-77-902 and knowingly made or caused to be made false claims to be made, used, and presented to the state of Arkansas by their violations of federal and state laws for the Affected Drug Products.

261. Compliance with applicable Medicare, Medicaid and various other federal and state laws was a condition of payment of claims submitted to the state of Arkansas. Had the state of Arkansas known that Gilead violated the laws cited herein, it would not have paid the claims submitted for the Affected Drug Products by health care providers and third party payers.

262. Distributing drugs within the state of Arkansas requires a valid license issued by the state of Arkansas. The license application contains a compliance statement. Had the state of Arkansas known that Gilead violated the laws cited herein, it would not have approved Gilead's application for a license and/or would have revoked Gilead's license.

263. The state of Arkansas has sustained damages as a result of Gilead's acts.

COUNT FOUR

VIOLATION OF THE CALIFORNIA FCA
CAL. GOV'T CODE § 12651(a)

264. Relators incorporate the allegations contained herein and hereby reallege them as set forth fully above.

265. Cal. Gov't Code § 12651(a) provides liability for any person who:

(1) Knowingly presents or causes to be presented a false or fraudulent claim for payment or approval.

(2) Knowingly makes, uses, or causes to be made or used a false record or statement material to a false or fraudulent claim.

266. Gilead violated Cal. Gov't Code § 12651(a) and knowingly made or caused to be made false claims to be made, used, and presented to the state of California by their violations of federal and state laws for the Affected Drug Products.

267. Compliance with applicable Medicare, Medi-Cal and various other federal and state laws was a condition of payment of claims submitted to the state of California. Had the state of California known that Gilead violated the laws cited herein, it would not have paid the claims for the Affected Drug Products submitted by health care providers and third party payers.

268. Distributing drugs within the state of California requires a valid license issued by the state of California. The license application contains a compliance statement. Had the state of California known that Gilead violated the laws cited herein, it would not have approved Gilead's application for a license and/or would have revoked Gilead's license.

269. The state of California has sustained damages as a result of Gilead's acts.

COUNT FIVE

VIOLATION OF THE DELAWARE FALSE CLAIMS ACT
Del. Code Ann. Tit. 6, § 1201

270. Relators incorporate the allegations contained herein and hereby reallege them as set forth fully above.

271. Del. Code Ann. Tit. 6, § 1201(a) provides liability for any person who:

(1) Knowingly presents, or causes to be presented a false or fraudulent claim for payment or approval;

(2) Knowingly makes, uses or causes to be made or used a false record or statement material to a false or fraudulent claim.

272. Gilead violated Del. Code Ann. Tit. 6, § 1201(a) and knowingly made or caused to be made false claims to be made, used, and presented to the state of Delaware by their violations of federal and state laws for the Affected Drug Products.

273. Compliance with applicable Medicare, Medicaid and various other federal and state laws was a condition of payment of claims submitted to the state of Delaware. Had the

state of Delaware known that Gilead violated the laws cited herein, it would not have paid the claims submitted for the Affected Drug Products by health care providers and third party payers.

274. Distributing drugs within the state of Delaware requires a valid license issued by the state of Delaware. Had the state of Delaware known that Gilead violated the laws cited herein, it would not have approved Gilead's application for a license and/or would have revoked Gilead's license.

275. The state of Delaware has sustained damages as a result of Gilead's acts.

COUNT SIX

VIOLATION OF THE DISTRICT OF COLUMBIA PROCUREMENT REFORM AMENDMENT ACT
D.C. Code Ann. § 2-381.01 *et seq.*

276. Relators incorporate the allegations contained herein and hereby reallege them as set forth fully above.

277. D.C. Code Ann. § 2-381.02(a) provides liability for any person who:

(a) Knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;

(b) Knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim.

278. Gilead violated D.C. Code Ann. § 2-381.02(a) and knowingly made or caused to be made false claims to be made, used, and presented to the District of Columbia by their violations of federal and state laws for the Affected Drug Products.

279. Compliance with applicable Medicare, Medicaid and various other federal and state laws was a condition of payment of claims for the Affected Drug Products submitted to the District of Columbia. Had the District known that Gilead violated the laws cited herein, it would not have paid the claims submitted by health care providers and third party payers.

280. The District of Columbia has sustained damages as a result of Gilead's acts.

COUNT SEVEN

VIOLATION OF THE FLORIDA FALSE CLAIMS ACT
Fla. Stat. Ann. § 68.081 *et seq.*

281. Relators incorporate the allegations contained herein and hereby reallege them as set forth fully above.

282. Fla. Stat. Ann. § 68.082(2) provides liability for any person who:

(a) Knowingly presents or causes to be presented a false or fraudulent claim for payment or approval;

(b) Knowingly makes, uses, or causes to be made or used a false record or statement material to a false or fraudulent claim.

283. Gilead violated Fla. Stat. Ann. § 68.082(2) and knowingly made or caused to be made false claims to be made, used, and presented to the state of Florida by their violations of federal and state laws for the Affected Drug Products.

284. Compliance with applicable Medicare, Medicaid and various other federal and state laws was a condition of payment of claims submitted to the state of Florida. Had the state of Florida known that Gilead violated the laws cited herein, it would not have paid the claims for the Affected Drug Products submitted by health care providers and third party payers.

285. Distributing drugs within the state of Florida requires a valid license issued by the state of Florida. This license requires the license-holder to expressly certify compliance with applicable food and drug laws and regulations. Had the state of Florida known that Gilead violated the laws cited herein, it would not have approved Gilead's application for a license and/or would have revoked Gilead's license.

286. The state of Florida has sustained damages as a result of Gilead's acts.

COUNT EIGHT

VIOLATION OF THE GEORGIA STATE FALSE MEDICAID CLAIMS ACT
Ga. Code Ann. § 49-4-168.1

287. Relators incorporate the allegations contained herein and hereby reallege them as set forth fully above.

288. Ga. Code Ann. § 49-4-168.1(a) provides liability for any person who:

(1) Knowingly presents or causes to be presented to the Georgia Medicaid program a false or fraudulent claim for payment or approval;

(2) Knowingly makes, uses, or causes to be made or used a false record or statement material to a false or fraudulent claim.

289. Gilead violated Ga. Code Ann. § 49-4-168.1 and knowingly made or caused to be made false claims to be made, used, and presented to the state of Georgia by their violations of federal and state laws for the Affected Drug Products.

290. Compliance with applicable Medicare, Medicaid and various other federal and state laws was a condition of payment of claims submitted to the state of Georgia. Had the state of Georgia known that Gilead violated the laws cited herein, it would not have paid the claims for the Affected Drug Products submitted by health care providers and third party payers.

291. Distributing drugs within the state of Georgia requires a valid license issued by the state of Georgia. The license application contains a compliance statement. Had the state of Georgia known that Gilead violated the laws cited herein, it would not have approved Gilead's application for a license and/or would have revoked Gilead's license.

292. The state of Georgia has sustained damages as a result of Gilead's acts.

COUNT NINE

VIOLATION OF THE HAWAII FALSE CLAIMS ACT
Haw. Rev. Stat. § 661-21

293. Relators incorporate the allegations contained herein and hereby reallege them as set forth fully above.

294. Haw. Rev. Stat. § 661-21(a) provides liability for any person who:

(1) Knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;

(2) Knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim.

295. Gilead violated Haw. Rev. Stat. § 661-21 and knowingly made or caused to be made false claims to be made, used, and presented to the state of Hawaii by their violations of federal and state laws for the Affected Drug Products.

296. Compliance with applicable Medicare, Medicaid and various other federal and state laws was a condition of payment of claims submitted to the state of Hawaii. Had the state of Hawaii known that Gilead violated the laws cited herein, it would not have paid the claims for the Affected Drug Products submitted by health care providers and third party payers.

297. Distributing drugs within the state of Hawaii requires a valid license issued by the state of Hawaii. The license application contains a compliance statement. Had the state of Hawaii known that Gilead violated the laws cited herein, it would not have approved Gilead's application for a license and/or would have revoked Gilead's license.

298. The state of Hawaii has sustained damages as a result of Gilead's acts.

COUNT TEN

VIOLATION OF THE ILLINOIS WHISTLEBLOWER REWARD AND PROTECTION ACT
740 Ill. Comp. Stat. 175/1 *et seq.*

299. Relators incorporate the allegations contained herein and hereby reallege them as set forth fully above.

300. 740 Ill. Comp. Stat. 175/3(a)(1) provides liability for any person who:

> (A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
>
> (B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim.

301. Gilead violated 740 Ill. Comp. Stat. 175/3(a) and knowingly made or caused to be made false claims to be made, used, and presented to the state of Illinois by their violations of federal and state laws for the Affected Drug Products.

302. Compliance with applicable Medicare, Medicaid and various other federal and state laws was a condition of payment of claims submitted to the state of Illinois. Had the state

of Illinois known that Gilead violated the laws cited herein, it would not have paid the claims for the Affected Drug Products submitted by health care providers and third party payers.

303. Distributing drugs within the state of Illinois requires a valid license issued by the state of Illinois. Had the state of Illinois known that Gilead violated the laws cited herein, it would not have approved Gilead's application for a license and/or would have revoked Gilead's license.

304. The state of Illinois has sustained damages as a result of Gilead's acts.

COUNT ELEVEN

VIOLATION OF THE INDIANA FALSE CLAIMS AND WHISTLEBLOWER PROTECTION ACT
Ind. Code Ann. § 5-11-5.5-1 *et seq.*

305. Relators incorporate the allegations contained herein and hereby reallege them as set forth fully above.

306. Ind. Code Ann. § 5-11-5.5-2(b) provides liability for any person who knowingly or intentionally:

> (1) presents a false claim to the state for payment or approval;
>
> (2) makes or uses a false record or statement to obtain payment or approval of a false claim from the state;
>
> * * *
>
> (8) causes or induces another person to perform an act described in subdivisions (1) through (6).

307. Gilead violated Ind. Code Ann. § 5-11-5.5-2(b) and knowingly made or caused to be made false claims to be made, used, and presented to the state of Indiana by their violations of federal and state laws for the Affected Drug Products.

308. Compliance with applicable Medicare, Medicaid and various other federal and state laws was a condition of payment of claims submitted to the state of Indiana. Had the state of Indiana known that Gilead violated the laws cited herein, it would not have paid the claims for the Affected Drug Products submitted by health care providers and third party payers.

309. Distributing drugs within the state of Indiana requires a valid license issued by the state of Indiana. Had the state of Indiana known that Gilead violated the laws cited herein, it would not have approved Gilead's application for a license and/or would have revoked Gilead's license.

310. The state of Indiana has sustained damages as a result of Gilead's acts.

COUNT TWELVE

VIOLATION OF THE LOUISIANA MEDICAL ASSISTANCE PROGRAMS INTEGRITY LAW
La. Rev. Stat. Ann. § 46:437.1 *et seq.*

311. Relators incorporate the allegations contained herein and hereby reallege them as set forth fully above.

312. La. Rev. Stat. Ann. § 46:438.3 provides that:

> A. No person shall knowingly present or cause to be presented a false or fraudulent claim.
>
> B. No person shall knowingly engage in misrepresentation or make, use, or cause to be made or used, a false record or statement material to a false or fraudulent claim.
>
> C. No person shall knowingly make, use, or cause to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the medical assistance programs . . . .
>
> D. No person shall conspire to defraud, or attempt to defraud, the medical assistance programs through misrepresentation or by obtaining, or attempting to obtain, payment for a false or fraudulent claim.

313. Gilead violated La. Rev. Stat. Ann. § 46:438.3 and knowingly made or caused to be made false claims to be made, used, and presented to the state of Louisiana by their violations of federal and state laws for the Affected Drug Products.

314. Compliance with applicable Medicare, Medicaid and various other federal and state laws was a condition of payment of claims submitted to the state of Louisiana. Had the state of Louisiana known that Gilead violated the laws cited herein, it would not have paid the claims for the Affected Drug Products submitted by health care providers and third party payers.

315. Distributing drugs within the state of Louisiana requires a valid license issued by the state of Louisiana. The license application contains a compliance statement. Had the state of Louisiana known that Gilead violated the laws cited herein, it would not have approved Gilead's application for a license and/or would have revoked Gilead's license.

316. The state of Louisiana has sustained damages as a result of Gilead's acts.

COUNT THIRTEEN

VIOLATION OF THE MASSACHUSETTS FALSE CLAIMS ACT
Mass. Gen. Laws Ann. ch. 12, § 5A *et seq.*

317. Relators incorporate the allegations contained herein and hereby reallege them as set forth fully above.

318. Mass. Gen. Laws Ann. ch. 12, § 5B provides liability for any person who:

> (1) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
>
> (2) knowingly makes, uses, or causes to be made or used a false record or statement material to a false or fraudulent claim;
>
> * * *
>
> (10) is a beneficiary of an inadvertent submission of a false claim to the commonwealth or a political subdivision thereof, or is a beneficiary of an overpayment from the commonwealth or a political subdivision thereof, and who subsequently discovers the falsity of the claim or the receipt of overpayment and fails to disclose the false claim or receipt of overpayment to the commonwealth . . . .

319. Gilead violated Mass. Gen. Laws Ann. ch. 12, § 5B and knowingly made or caused to be made false claims to be made, used, and presented to the commonwealth of Massachusetts by their violations of federal and state laws for the Affected Drug Products.

320. Compliance with applicable Medicare, Medicaid and various other federal and state laws was a condition of payment of claims submitted to the commonwealth of Massachusetts. Had the commonwealth of Massachusetts known that Gilead violated the laws cited herein, it would not have paid the claims for the Affected Drug Products submitted by health care providers and third party payers.

321. Distributing drugs within the state of Massachusetts requires a valid license issued by the state of Massachusetts. Had the state of Massachusetts known that Gilead violated the laws cited herein, it would not have approved Gilead's application for a license and/or would have revoked Gilead's license.

322. The commonwealth of Massachusetts has sustained damages as a result of Gilead's acts.

COUNT FOURTEEN

VIOLATION OF THE MICHIGAN MEDICAID FALSE CLAIMS ACT
Mich. Comp. Laws § 400.601 *et seq.*

323. Relators incorporate the allegations contained herein and hereby reallege them as set forth fully above.

324. Mich. Comp. Laws § 400.603 states that:

> (1) A person shall not knowingly make or cause to be made a false statement or false representation of a material fact in an application for medicaid benefits.
>
> (2) A person shall not knowingly make or cause to be made a false statement or false representation of a material fact for use in determining rights to a medicaid benefit.
>
> (3) A person, who having knowledge of the occurrence of an event affecting his initial or continued right to receive a medicaid benefit or the initial or continued right of any other person on whose behalf he has applied for or is receiving a benefit, shall not conceal or fail to disclose that event with intent to obtain a benefit to which the person or any other person is not entitled or in an amount greater than that to which the person or any other person is entitled.

325. Mich. Comp. Laws § 400.607 states that:

> (1) A person shall not make or present or cause to be made or presented to an employee or officer of this state a claim under the social welfare act, 1939 PA 280, MCL 400.1 to 400.119b, upon or against the state, knowing the claim to be false.

326. Gilead violated Mich. Comp. Laws §§ 400.603 & 400.607 and knowingly made or caused to be made false claims to be made, used, and presented to the state of Michigan by their violations of federal and state laws for the Affected Drug Products.

327. Compliance with applicable Medicare, Medicaid and various other federal and state laws was a condition of payment of claims submitted to the state of Michigan. Had the state of Michigan known that Gilead violated the laws cited herein, it would not have paid the claims for the Affected Drug Products submitted by health care providers and third party payers.

328. Distributing drugs within the state of Michigan requires a valid license issued by the state of Michigan. This license requires the license-holder to expressly certify compliance with applicable food and drug laws and regulations. Had the state of Michigan known that Gilead violated the laws cited herein, it would not have approved Gilead's application for a license and/or would have revoked Gilead's license.

329. The state of Michigan has sustained damages as a result of Gilead's acts.

COUNT FIFTEEN

VIOLATION OF THE MONTANA FALSE CLAIMS ACT
Mont. Code Ann. § 17-8-401 *et seq.*

330. Relators incorporate the allegations contained herein and hereby reallege them as set forth fully above.

331. Mont. Code Ann. § 17-8-403 provides liability for any person who:

(a) knowingly presents or causes to be presented a false or fraudulent claim for payment or approval;

(b) knowingly makes, uses, or causes to be made or used a false record or statement material to a false or fraudulent claim.

332. Gilead violated Mont. Code Ann. § 17-8-403 and knowingly made or caused to be made false claims to be made, used, and presented to the state of Montana by their violations of federal and state laws for the Affected Drug Products.

333. Compliance with applicable Medicare, Medicaid and various other federal and state laws was a condition of payment of claims submitted to the state of Montana. Had the state of Montana known that Gilead violated the laws cited herein, it would not have paid the claims for the Affected Drug Products submitted by health care providers and third party payers.

334. Distributing drugs within the state of Montana requires a valid license issued by the state of Montana. The license application contains a compliance statement. Had the state of Montana known that Gilead violated the laws cited herein, it would not have approved Gilead's application for a license and/or would have revoked Gilead's license.

335. The state of Montana has sustained damages as a result of Gilead's acts.

COUNT SIXTEEN

VIOLATION OF THE NEVADA FALSE CLAIMS ACT
Nev. Rev. Stat. Ann. § 357.010 *et seq.*

336. Relators incorporate the allegations contained herein and hereby reallege them as set forth fully above.

337. Nev. Rev. Stat. Ann. § 357.040(1) provides liability for any person who:

> (a) knowingly presents or causes to be presented a false or fraudulent claim for payment or approval;
>
> (b) knowingly makes or uses, or causes to be made or used, a false record or statement that is material to a false or fraudulent claim.
>
> * * *
>
> (h) is a beneficiary of an inadvertent submission of a false claim and, after discovering the falsity of the claim, fails to disclose the falsity to the State or political subdivision within a reasonable time.

338. Gilead violated Nev. Rev. Stat. Ann. § 357.040 and knowingly made or caused to be made false claims to be made, used, and presented to the state of Nevada by their violations of federal and state laws for the Affected Drug Products.

339. Compliance with applicable Medicare, Medicaid and various other federal and state laws was a condition of payment of claims submitted to the state of Nevada. Had the state of Nevada known that Gilead violated the laws cited herein, it would not have paid the claims for the Affected Drug Products submitted by health care providers and third party payers.

340. Distributing drugs within the state of Nevada requires a valid license issued by the state of Nevada. The license application contains a compliance statement. Had the state of

Nevada known that Gilead violated the laws cited herein, it would not have approved Gilead's application for a license and/or would have revoked Gilead's license.

341. The state of Nevada has sustained damages as a result of Gilead's acts.

COUNT SEVENTEEN

VIOLATION OF THE NEW HAMPSHIRE FALSE CLAIMS ACT
N.H. Rev. Stat. Ann. § 167:61 *et seq.*

342. Relators incorporate the allegations contained herein and hereby reallege them as set forth fully above.

343. N.H. Rev. Stat. Ann. § 167:61-b(I) provides liability for any person who:

> (a) knowingly presents, or causes to be presented, to an officer or employee of the department, a false or fraudulent claim for payment or approval.
>
> (b) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the department.
>
> (c) conspires to defraud the department by getting a false or fraudulent claim allowed or paid.
>
> * * *
>
> (f) is a beneficiary of an inadvertent submission of a false claim to the department, who subsequently discovers the falsity of the claim, and fails to disclose the false claim to the department within a reasonable time after discovery of the false claim

344. Gilead violated N.H. Rev. Stat. Ann. § 167:61-b(I) and knowingly made or caused to be made false claims to be made, used, and presented to the state of New Hampshire by their violations of federal and state laws for the Affected Drug Products.

345. Compliance with applicable Medicare, Medicaid and various other federal and state laws was a condition of payment of claims submitted to the state of New Hampshire. Had the state of New Hampshire known that Gilead violated the laws cited herein, it would not have paid the claims for the Affected Drug Products submitted by health care providers and third party payers.

346. Distributing drugs within the state of New Hampshire requires a valid license issued by the state of New Hampshire. The license application contains a compliance statement. Had the state of New Hampshire known that Gilead violated the laws cited herein, it would not have approved Gilead's application for a license and/or would have revoked Gilead's license.

347. The state of New Hampshire has sustained damages as a result of Gilead's acts.

COUNT EIGHTEEN

VIOLATION OF THE NEW JERSEY FALSE CLAIMS ACT
N.J. Stat. Ann. § 2A:32C-1 *et seq.*

348. Relators incorporate the allegations contained herein and hereby reallege them as set forth fully above.

349. N.J. Stat. Ann. § 2A:32C-3 provides liability for any person who:

(a) knowingly presents or causes to be presented to an employee, officer, or agent of the State, or to any contractor, grantee, or other recipient of State funds, a false or fraudulent claim for payment or approval;

(b) knowingly makes, uses, or causes to be made or used a false record or statement to get a false or fraudulent claim paid or approved by the State.

350. Gilead violated N.J. Stat. Ann. § 2A:32C-3 and knowingly made or caused to be made false claims to be made, used, and presented to the state of New Jersey by their violations of federal and state laws for the Affected Drug Products.

351. Compliance with applicable Medicare, Medicaid and various other federal and state laws was a condition of payment of claims submitted to the state of New Jersey. Had the state of New Jersey known that Gilead violated the laws cited herein, it would not have paid the claims for the Affected Drug Products submitted by health care providers and third party payers.

352. Distributing drugs within the state of New Jersey requires a valid license issued by the state of New Jersey. The license application contains a compliance statement. Had the state of New Jersey known that Gilead violated the laws cited herein, it would not have approved Gilead's application for a license and/or would have revoked Gilead's license.

353. The state of New Jersey has sustained damages as a result of Gilead's acts.

COUNT NINETEEN

VIOLATION OF THE NEW MEXICO FALSE CLAIMS ACT
N.M. Stat. Ann. §§ 27-14-1 *et seq.* & 44-9-3 *et seq.*

354. Relators incorporate the allegations contained herein and hereby reallege them as set forth fully above.

355. N.M. Stat. Ann. § 27-14-4 provides liability for any person who:

> A. presents, or causes to be presented, to the state a claim for payment under the medicaid program knowing that such claim is false or fraudulent;
>
> * * *
>
> C. makes, uses or causes to be made or used a record or statement to obtain a false or fraudulent claim under the medicaid program paid for or approved by the state knowing such record or statement is false.

356. N.M. Stat. Ann. § 44-9-3(A) provides liability for persons who:

> (1) knowingly present, or cause be presented, to an employee, officer or agent of the state or to a contractor, grantee or other recipient of state funds a false or fraudulent claim for payment or approval;
>
> (2) knowingly make or use, or cause to be made or used, a false, misleading or fraudulent record or statement to obtain or support the approval of or the payment on a false or fraudulent claim;
>
> * * *
>
> (9) as a beneficiary of an inadvertent submission of a false claim and having subsequently discovered the falsity of the claim, fail to disclose the false claim to the state within a reasonable time after discovery.

357. Gilead violated N.M. Stat. Ann. §§ 27-14-4 & 44-9-3 and knowingly made or caused to be made false claims to be made, used, and presented to the state of New Mexico by their violations of federal and state laws for the Affected Drug Products.

358. Compliance with applicable Medicare, Medicaid and various other federal and state laws was a condition of payment of claims submitted to the state of New Mexico. Had the state of New Mexico known that Gilead violated the laws cited herein, it would not have paid the claims for the Affected Drug Products submitted by health care providers and third party payers.

359. Distributing drugs within the state of New Mexico requires a valid license issued by the state of New Mexico. The license application contains a compliance statement. Had the state of New Mexico known that Gilead violated the laws cited herein, it would not have approved Gilead's application for a license and/or would have revoked Gilead's license.

360. The state of New Mexico has sustained damages as a result of Gilead's acts.

COUNT TWENTY

VIOLATION OF THE NEW YORK FALSE CLAIMS ACT N.Y. State Fin. §§ 187-194

361. Relators incorporate the allegations contained herein and hereby reallege them as set forth fully above.

362. N.Y. State Fin. § 189(1) provides liability for any person who:

(a) knowingly presents, or causes to be presented a false or fraudulent claim for payment or approval;

(b) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim.

363. Gilead violated N.Y. State Fin. § 189 and knowingly made or caused to be made false claims to be made, used, and presented to the state of New York by their violations of federal and state laws for the Affected Drug Products.

364. Compliance with applicable Medicare, Medicaid and various other federal and state laws was a condition of payment of claims submitted to the state of New York. Had the state of New York known that Gilead violated the laws cited herein, it would not have paid the claims for the Affected Drug Products submitted by health care providers and third party payers.

365. Distributing drugs within the state of New York requires a valid license issued by the state of New York. The license application contains a compliance statement. Had the state of New York known that Gilead violated the laws cited herein, it would not have approved Gilead's application for a license and/or would have revoked Gilead's license.

366. The state of New York has sustained damages as a result of Gilead's acts.

COUNT TWENTY-ONE

VIOLATION OF THE OKLAHOMA MEDICAID FALSE CLAIMS ACT
Okla. Stat. tit. 56, §§ 1005-07 & tit. 63, § 5053 *et seq.*

367. Relators incorporate the allegations contained herein and hereby reallege them as set forth fully above.

368. Okla. Stat. tit. 63, § 5053.1(B) provides liability for any person who:

1. Knowingly presents, or causes to be presented, to an officer or employee of the State of Oklahoma, a false or fraudulent claim for payment or approval.

369. Okla. Stat. tit. 56, § 1005(A) provides liability for persons who:

1. Make or cause to be made a claim, knowing the claim to be false, in whole or in part, by commission or omission;

2. Make or cause to be made a statement or representation for use in obtaining or seeking to obtain authorization to provide a good or a service knowing the statement or representation to be false, in whole or in part, by commission or omission;

3. Make or cause to be made a statement or representation for use by another in obtaining a good or a service under the Oklahoma Medicaid Program, knowing the statement or representation to be false, in whole or in part, by commission or omission;

* * *

6. Solicit or accept a benefit, pecuniary benefit, or kickback in connection with goods or services paid or claimed by a provider to be payable by the Oklahoma Medicaid Program.

370. Gilead violated Okla. Stat. tit. 56, § 1005 & tit. 63, § 5053.1(B) and knowingly made or caused to be made false claims to be made, used, and presented to the state of Oklahoma by their violations of federal and state laws for the Affected Drug Products.

371. Compliance with applicable Medicare, Medicaid and various other federal and state laws was a condition of payment of claims submitted to the state of Oklahoma. Had the state of Oklahoma known that Gilead violated the laws cited herein, it would not have paid the claims for the Affected Drug Products submitted by health care providers and third party payers.

372. The state of Oklahoma has sustained damages as a result of Gilead's acts.

COUNT TWENTY-TWO

VIOLATION OF THE RHODE ISLAND FALSE CLAIMS ACT
R.I. Gen. Laws § 9-1.1 et seq.

373. Relators incorporate the allegations contained herein and hereby reallege them as set forth fully above.

374. R.I. Gen. Laws § 9-1.1-3 provides liability for any person who:

(1) Knowingly presents, or causes to be presented a false or fraudulent claim for payment or approval;

(2) Knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;

* * *

(5) Is authorized to make or deliver a document certifying receipt of property used, or to be used, by the state and, intending to defraud the state, makes or delivers the receipt without completely knowing that the information on the receipt is true;

* * *

(7) Knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the state, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the state.

375. Gilead violated R.I. Gen. Laws § 9-1.1-3 and knowingly made or caused to be made false claims to be made, used, and presented to the state of Rhode Island by their violations of federal and state laws for the Affected Drug Products.

376. Compliance with applicable Medicare, Medicaid and various other federal and state laws was a condition of payment of claims submitted to the state of Rhode Island. Had the state of Rhode Island known that Gilead violated the laws cited herein, it would not have paid the claims for the Affected Drug Products submitted by health care providers and third party payers.

377. Distributing drugs within the state of Rhode Island requires a valid license issued by the state of Rhode Island. The license application contains a compliance statement. Had the

state of Rhode Island known that Gilead violated the laws cited herein, it would not have approved Gilead's application for a license and/or would have revoked Gilead's license.

378. The state of Rhode Island has sustained damages as a result of Gilead's acts.

COUNT TWENTY-THREE

VIOLATION OF THE TENNESSEE MEDICAID FALSE CLAIMS ACT
Tenn. Code Ann. § 71-5-181 *et seq.*

379. Relators incorporate the allegations contained herein and hereby reallege them as set forth fully above.

380. Tenn. Code Ann. § 71-5-182(a)(1) provides liability for any person who:

(A) Knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval under the medicaid program;

(B) Knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim under the medicaid program.

381. Gilead violated Tenn. Code Ann. § 71-5-182(a)(1) and knowingly made or caused to be made false claims to be made, used, and presented to the state of Tennessee by their violations of federal and state laws for the Affected Drug Products.

382. Compliance with applicable Medicare, Medicaid and various other federal and state laws was a condition of payment of claims submitted to the state of Tennessee. Had the state of Tennessee known that Gilead violated the laws cited herein, it would not have paid the claims for the Affected Drug Products submitted by health care providers and third party payers.

383. Distributing drugs within the state of Tennessee requires a valid license issued by the state of Tennessee. The license application contains a compliance statement. Had the state of Tennessee known that Gilead violated the laws cited herein, it would not have approved Gilead's application for a license and/or would have revoked Gilead's license.

384. The state of Tennessee has sustained damages as a result of Gilead's acts.

COUNT TWENTY-FOUR

VIOLATION OF THE TEXAS MEDICAID FRAUD PREVENTION LAW
Tex. Hum. Res. Code Ann. § 36.001 *et seq.*

385. Relators incorporate the allegations contained herein and hereby reallege them as set forth fully above.

386. Tex. Hum. Res. Code Ann. § 36.002 provides liability for any person who:

(1) knowingly makes or causes to be made a false statement or misrepresentation of a material fact to permit a person to receive a benefit or payment under the Medicaid program that is not authorized or that is greater than the benefit or payment that is authorized;

(2) knowingly conceals or fails to disclose information that permits a person to receive a benefit or payment under the Medicaid program that is not authorized or that is greater than the benefit or payment that is authorized;

(3) knowingly applies for and receives a benefit or payment on behalf of another person under the Medicaid program and converts any part of the benefit or payment to a use other than for the benefit of the person on whose behalf it was received;

387. 25 Tex. Admin. Code § 229.429 provides that:

(a) . . . All persons engaged in the wholesale distribution of prescription drugs must comply with the applicable minimum standards in this section, in addition to the statutory requirements contained in the Texas Food, Drug, and Cosmetic Act, Health and Safety Code, Chapter 431 [] and those requirements in §229.420 of this title . . . .

* * *.

(c) . . . Manufacturers of prescription drug products shall be in compliance with the applicable requirements in 21 CFR, Part 210, titled "Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding of Drugs"; 21 CFR, Part 211, titled "Current Good Manufacturing Practice for Finished Pharmaceuticals; General" . . . . The regulations in these parts govern the methods used in, and the facilities or controls used for, the manufacture, processing, packing, or holding of a drug to assure that each drug meets the requirements of the Federal Act as to safety, and has the identity and strength and meets the quality and purity characteristics that it purports or is represented to possess.

388. Gilead violated Tex. Hum. Res. Code Ann. § 36.002 and 25 Tex. Admin. Code § 229.429 and knowingly made or caused to be made false claims to be made, used, and presented to the state of Texas by their violations of federal and state laws for the Affected Drug Products.

389. Compliance with applicable Medicare, Medicaid and various other federal and state laws was a condition of payment of claims submitted to the state of Texas. Had the state of Texas known that Gilead violated the laws cited herein, it would not have paid the claims for the Affected Drug Products submitted by health care providers and third party payers.

390. Distributing drugs within the state of Texas requires a valid license issued by the state of Texas. This license expressly requires the license-holder to certify compliance with applicable food and drug laws and regulations. Had the state of Texas known that Gilead violated the laws cited herein, it would not have approved Gilead's application for a license and/or would have revoked Gilead's license. See Tex. Admin. Code § 229.428.

391. The state of Texas has sustained damages as a result of Gilead's acts.

COUNT TWENTY-FIVE

VIOLATION OF THE VIRGINIA FRAUD AGAINST TAXPAYERS ACT
Va. Code Ann. § 8.01-216.1 *et seq.*

392. Relators incorporate the allegations contained herein and hereby reallege them as set forth fully above.

393. Va. Code Ann. § 8.01-216.3 provides liability for any person who:

> 1. Knowingly presents, or causes to be presented a false or fraudulent claim for payment or approval;
>
> 2. Knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;
>
> * * *
>
> 4. Has possession, custody, or control of property or money used, or to be used, by the Commonwealth and knowingly delivers, or causes to be delivered, less than all such money or property;
>
> 5. Is authorized to make or deliver a document certifying receipt of property used, or to be used, by the Commonwealth and, intending to defraud the

Commonwealth, makes or delivers the receipt without completely knowing that the information on the receipt is true;

6. Knowingly buys or receives as a pledge of an obligation or debt, public property from an officer or employee of the Commonwealth who lawfully may not sell or pledge the property; or

7. Knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Commonwealth or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Commonwealth.

394. Gilead violated Va. Code Ann. § 8.01-216.3 and knowingly made or caused to be made false claims to be made, used, and presented to the commonwealth of Virginia by their violations of federal and state laws for the Affected Drug Products.

395. Compliance with applicable Medicare, Medicaid and various other federal and state laws was a condition of payment of claims submitted to the commonwealth of Virginia. Had the commonwealth of Virginia known that Gilead violated the laws cited herein, it would not have paid the claims for the Affected Drug Products submitted by health care providers and third party payers.

396. Distributing drugs within the state of Virginia requires a valid license issued by the state of Virginia. This license requires the license-holder to certify compliance with applicable food and drug laws and regulations. Had the state of Virginia known that Gilead violated the laws cited herein, it would not have approved Gilead's application for a license and/or would have revoked Gilead's license.

397. The commonwealth of Virginia has sustained damages as a result of Gilead's acts.

COUNT TWENTY-SIX

VIOLATION OF THE UTAH FALSE CLAIMS ACT
Utah Code Ann. § 26-20-1 *et seq.*

398. Relators incorporate the allegations contained herein and hereby reallege them as set forth fully above.

399. Utah Code Ann. § 26-20-7 provides liability for persons who:

> (1) . . . present or cause to be made or presented to an employee or officer of the state a claim for a medical benefit:
>
> (a) which is wholly or partially false, fictitious, or fraudulent;
>
> * * *
>
> (c) which misrepresents the type, quality, or quantity of items or services rendered;
>
> * * *
>
> (2) . . . a person may not:
>
> * * *
>
> (c) falsify or alter with intent to deceive, any report or document required by state or federal law, rule, or Medicaid provider agreement;
>
> (d) retain any unauthorized payment as a result of acts described in this section; or
>
> (e) aid or abet the commission of any act prohibited by this section.

400. Gilead violated Utah Code Ann. § 26-20-7 and knowingly made or caused to be made false claims to be made, used, and presented to the state of Utah by their violations of federal and state laws for the Affected Drug Products.

401. Compliance with applicable Medicare, Medicaid and various other federal and state laws was a condition of payment of claims submitted to the state of Utah. Had the state of Utah known that Gilead violated the laws cited herein, it would not have paid the claims for the Affected Drug Products submitted by health care providers and third party payers.

402. Distributing drugs within the state of Utah requires a valid license issued by the state of Utah. The license application contains a compliance statement. Had the state of Utah known that Gilead violated the laws cited herein, it would not have approved Gilead's application for a license and/or would have revoked Gilead's license.

403. The state of Utah has sustained damages as a result of Gilead's acts.

COUNT TWENTY-SEVEN

VIOLATION OF THE WISCONSIN FALSE CLAIMS FOR MEDICAL ASSISTANCE LAW
Wis. Code Ann. § 20.931 *et seq.*

404. Relators incorporate the allegations contained herein and hereby reallege them as set forth fully above.

405. Wis. Code Ann. § 20.931(2) provides liability for any person who:

(a) Knowingly presents or causes to be presented to any officer, employee, or agent of this state a false claim for medical assistance;

(b) Knowingly makes, uses, or causes to be made or used a false record or statement to obtain approval or payment of a false claim for medical assistance.

406. Gilead violated Wis. Code Ann. § 20.931(2) and knowingly made or caused to be made false claims to be made, used, and presented to the state of Wisconsin by their violations of federal and state laws for the Affected Drug Products.

407. Compliance with applicable Medicare, Medicaid and various other federal and state laws was a condition of payment of claims submitted to the state of Wisconsin. Had the state of Wisconsin known that Gilead violated the laws cited herein, it would not have paid the claims for the Affected Drug Products submitted by health care providers and third party payers.

408. Distributing drugs within the state of Wisconsin requires a valid license issued by the state of Wisconsin. Had the state of Wisconsin known that Gilead violated the laws cited herein, it would not have approved Gilead's application for a license and/or would have revoked Gilead's license.

409. The state of Wisconsin has sustained damages as a result of Gilead's acts.

COUNT TWENTY-EIGHT

VIOLATION OF THE CHICAGO FALSE CLAIMS ACT
Municipal Code, tit. 1, ch. 1-21 *et seq.*

410. Relators incorporate the allegations contained herein and hereby reallege them as set forth fully above.

411. Municipal Code, tit. 1, ch. 1-21-010 provides liability for "[a]ny person who knowingly makes a false statement of material fact to the city in violation of any statute, ordinance or regulation, or who knowingly makes a false statement of material fact to the city in connection with any application, report, affidavit, oath, or attestation, including a statement of material fact made in connection with a bid, proposal, contract or economic disclosure statement or affidavit . . . ."

412. Gilead violated Municipal Code, tit. 1, ch 1-21-010 and knowingly made or caused to be made false claims to be made, used, and presented to the city of Chicago by their violations of federal and state laws for the Affected Drug Products.

413. Compliance with applicable Medicare, Medicaid and various other federal and state laws was a condition of payment of claims submitted to the city of Chicago. Had the city of Chicago known that Gilead violated the laws cited herein, it would not have paid the claims for the Affected Drug Products submitted by health care providers and third party payers.

414. The city of Chicago has sustained damages as a result of Gilead's acts.

COUNT TWENTY-NINE

RETALIATION/TERMINATION IN VIOLATION OF THE FALSE CLAIMS ACT 31 U.S.C. § 3730(h)

415. Relators incorporate the allegations contained herein and hereby reallege them as set forth fully above.

416. 31 U.S.C. § 3730(h)(1) provides that:

> Any employee . . . shall be entitled to all relief necessary to make that employee . . . whole, if that employee . . . is discharged, demoted, suspended, threatened, harassed, or in any other manner discriminated against in the terms and conditions of employment because of lawful acts done by the employee . . . or associated others in furtherance of an action under this section or other efforts to stop 1 or more violations of this subchapter.

417. As alleged above, Gilead violated 31 U.S.C. § 3730(h) by harassing Mr. Campie; demoting and stripping Mr. Campie of his job duties, including, but not limited to, ostracizing him from the regulatory submission review process and removing him from his position on the

company's Quality Council; and ultimately terminating his employment. Gilead took these adverse employment actions against Mr. Campie because he discovered, investigated, and raised concerns over Gilead's release and distribution (much of it for commercial sale in the United States and paid for by the Government and the States under the Government Payments Programs) of tons of contaminated and adulterated API that had been manufactured at an unregistered and uninspected CMO; that had not properly been demonstrated to be (and in fact was not) equivalent to FDA-approved API; that was of substandard strength, quality, purity, potency, safety and/or efficaciousness; that had been used to submit falsified testing, data, and statements to the FDA; and that had been used to manufacture the Affected Drug Products which were not approved under the FDCA and thus were not eligible for payment under the Government Payment Programs, causing the submission of false claims paid by the Government and the States.

418. As a proximate result, Mr. Campie suffered damages in an amount to be determined at trial.

COUNT THIRTY

WHISTLEBLOWER RETALIATION
Cal. Lab. Code § 1102.5

419. Relators incorporate the allegations contained herein and hereby reallege them as set forth fully above.

420. Cal. Lab. Code § 1102.5 provides

> (b) An employer, or any person acting on behalf of the employer, shall not retaliate against an employee for disclosing information, or because the employer believes that the employee disclosed or may disclose information, to a government or law enforcement agency, to a person with authority over the employee or another employee who has the authority to investigate, discover, or correct the violation or noncompliance, or for providing information to, or testifying before, any public body conducting an investigation, hearing, or inquiry, if the employee has reasonable cause to believe that the information discloses a violation of state or federal statute, or a violation of or noncompliance with a local, state, or federal rule or regulation,

> regardless of whether disclosing the information is part of the employee's job duties.
>
> (c) An employer, or any person acting on behalf of the employer, shall not retaliate against an employee for refusing to participate in an activity that would result in a violation of state or federal statute, or a violation of or noncompliance with a local, state, or federal rule or regulation.

421. As explained above, Gilead violated Cal. Lab. Code § 1102.5 by retaliating against Mr. Campie (1) for having reported numerous violations of state and federal statutes and regulations that govern the manufacture (and subsequent distribution and commercial sale to the Government and States through the Government Payment Programs), including, but not limited to the federal FDCA; federal regulations including cGMPs set forth in 21 C.F.R. parts 210 & 211; the federal FCA; the California False Claims Act; and California's Sherman Food, Drug, and Cosmetic Law; and (2) for having refused to participate in the illegal manufacture, processing, release, and distribution of drug product in violation of the same.

422. Acts of retaliation under Cal. Lab. Code § 1102.5 are set forth above, and include, but are not limited to harassing Mr. Campie; demoting and stripping Mr. Campie of his job duties, including, but not limited to, ostracizing him from the regulatory submission review process and removing him from his position on the company's Quality Council; and ultimately terminating his employment. Gilead took these adverse employment actions against Mr. Campie because he discovered, investigated, and raised concerns over Gilead's release and distribution (much of it for commercial sale in the United States and paid for by Government and the States under the Government Payments Programs) of tons of contaminated and adulterated API that had been manufactured at an unregistered and uninspected CMO; that had not properly been demonstrated to be (and in fact was not) equivalent to FDA-approved API; that was of substandard strength, quality, purity, potency, safety and/or efficaciousness; that had been used to submit falsified testing, data, and statements to the FDA; and that had been used to manufacture the Affected Drug Products which were not approved under the FDCA and thus were not eligible for payment under the Government Payment Programs, causing the submission of false claims paid by the Government and the States.

423. As a proximate result, Mr. Campie suffered damages in an amount to be determined at trial.

COUNT THIRTY-ONE

RETALIATION
Cal. Lab. Code § 98.6

424. Relators incorporate the allegations contained herein and hereby reallege them as set forth fully above.

425. Cal. Lab. Code § 98.6(a) provides that:

> A person shall not discharge an employee or in any manner discriminate, retaliate, or take any adverse action against any employee . . . because the employee . . . engaged in any conduct delineated in this chapter . . . .

426. Gilead violated Cal. Lab. Code § 98.6 by retaliating, discriminating, and/or taking adverse action against Mr. Campie for having engaged in protected whistleblowing activities, as explained above. Protected whistleblowing acts in which Mr. Campie engaged include having reported numerous violations of state and federal statutes and regulations that govern the manufacture (and subsequent distribution and commercial sale to the Government and the State through the Government Payments Programs), including, but not limited to the federal FDCA; federal regulations including cGMPs set forth in 21 C.F.R. parts 210 & 211; the federal FCA; the California False Claims Act; and California's Sherman Food, Drug, and Cosmetic Law.

427. Acts of retaliation, discrimination, and adverse action under Cal. Lab. Code § 98.6 are set forth above, and include, but are not limited to harassing Mr. Campie; demoting and stripping Mr. Campie of his job duties, including, but not limited to, ostracizing him from the regulatory submission review process and removing him from his position on the company's Quality Council; and ultimately terminating his employment. Defendant took these adverse employment actions against Mr. Campie because he discovered, investigated, and raised concerns over Gilead's release and distribution (much of it for commercial sale in the United States and paid for by Government and the States under the Government Payments Programs) of

tons of contaminated and adulterated API that had been manufactured at an unregistered and uninspected CMO; that had not properly been demonstrated to be (and in fact was not) equivalent to FDA-approved API; that was of substandard strength, quality, purity, potency, safety and/or efficaciousness; that had been used to submit falsified testing, data, and statements to the FDA; and that had been used to manufacture the Affected Drug Products which were not approved under the FDCA and thus were not eligible for payment under the Government Payment Programs, causing the submission of false claims paid by the Government and the States.

428. As a proximate result, Mr. Campie suffered damages in an amount to be determined at trial.

COUNT THIRTY-TWO

TERMINATION IN VIOLATION OF CALIFORNIA PUBLIC POLICY

429. Relators incorporate the allegations contained herein and hereby reallege them as set forth fully above.

430. As explained above, Mr. Campie's termination from his employment with Gilead was based upon Gilead's violation of the public policy of the state of California, as set forth in Cal. Lab. Code § 1102.5, 98.6, the California Constitution, and other statutes and provisions.

431. As a proximate results, Mr. Campie suffered damages in an amount to be determined at trial.

PRAYER FOR RELIEF

432. WHEREFORE Relators, on behalf of themselves, the Government and the States, pray:

433. Judgment in an amount equal to threefold the damages to be proven at trial against Gilead and in favor of the United States, plus a civil penalty of up to $11,000 for each violation of 31 U.S.C. §3729;

434. Judgment in an amount equal to threefold the damages to be proven at trial against Gilead and in favor of the State of Arkansas, plus a civil penalty of up to $10,000 for each violation of Ark. Code Ann. § 20-77-902;

435. Judgment in an amount equal to threefold the damages to be proven at trial against Gilead and in favor of the State of California, plus a civil penalty of up to $10,000 for each violation of Cal. Govt. Code § 12651(a);

436. Judgment in an amount equal to threefold the damages to be proven at trial against Gilead and in favor of the State of Delaware, plus a civil penalty of up to $11,000 for each violation of Del. Code Ann. tit. 6, § 1201(a);

437. Judgment in an amount equal to threefold the damages to be proven at trial against Gilead and in favor of the District of Columbia, plus a civil penalty of up to $10,000 for each violation of D.C. Code Ann. § 2-381-02(a);

438. Judgment in an amount equal to threefold the damages to be proven at trial against Gilead and in favor of the State of Florida, plus a civil penalty of up to $10,000 for each violation of Fla. Stat. Ann. § 68.082(2);

439. Judgment in an amount equal to threefold the damages to be proven at trial against Gilead and in favor of the State of Georgia, plus a civil penalty of up to $11,000 for each violation of Ga. Code Ann. § 49-4-168.1;

440. Judgment in an amount equal to threefold the damages to be proven at trial against Gilead and in favor of the State of Hawaii, plus a civil penalty of up to $10,000 for each violation of Haw. Rev. Stat. § 661-21;

441. Judgment in an amount equal to threefold the damages to be proven at trial against Gilead and in favor of the State of Illinois, plus a civil penalty of up to $10,000 for each violation of 740 Ill. Comp. Stat. § 175/3(a);

442. Judgment in an amount equal to threefold the damages to be proven at trial against Gilead and in favor of the State of Indiana, plus a civil penalty of up to $5,000 for each violation of Ind. Code Ann. § 5-11-5.5-2(b);

443. Judgment in an amount equal to the damages to be proven at trial against Gilead and in favor of the State of Louisiana, plus a civil fine in the amount of three times the amount of action damages sustained for each violation of La. Rev. Stat. Ann. § 46:438.3;

444. Judgment in an amount equal to threefold the damages to be proven at trial against Gilead and in favor of the State of Massachusetts, plus a civil penalty of up to $10,000 for each violation of Mass. Gen. Laws Ann. ch. 12, § 5B;

445. Judgment in an amount equal to threefold the damages to be proven at trial against Gilead and in favor of the State of Michigan, plus a civil penalty of up to $10,000 for each violation of Mich. Comp. Laws §§ 400.603 & 400.607;

446. Judgment in an amount equal to threefold the damages to be proven at trial against Gilead and in favor of the State of Montana, plus a civil penalty of up to $10,000 for each violation of Mont. Code Ann. § 17-8-403;

447. Judgment in an amount equal to threefold the damages to be proven at trial against Gilead and in favor of the State of Nevada, plus a civil penalty of up to $10,000 for each violation of Nev. Rev. Stat. Ann. § 357.040;

448. Judgment in an amount equal to threefold the damages to be proven at trial against Gilead and in favor of the State of New Hampshire, plus a civil penalty of up to $10,000 for each violation of N.H. Rev. Stat. Ann. § 167:61-b(I);

449. Judgment in an amount equal to threefold the damages to be proven at trial against Gilead and in favor of the State of New Jersey, plus civil penalties for each violation of N.J. Stat. Ann. § 2A:32C-3;

450. Judgment in an amount equal to threefold the damages to be proven at trial against Gilead and in favor of the State of New Mexico, plus a civil penalty for each violation of N.M. Stat. Ann. §§ 27-14-4 & 44-9-3;

451. Judgment in an amount equal to threefold the damages to be proven at trial against Gilead and in favor of the State of New York, plus a civil penalty of up to $10,000 for each violation of N.Y. State Fin. § 189;

452. Judgment in an amount equal to threefold the damages to be proven at trial against Gilead and in favor of the State of Oklahoma, plus a civil penalty of up to $10,000 for each violation of Okla. Stat. tit. 56, § 1005 & tit. 63 § 5053;

453. Judgment in an amount equal to threefold the damages to be proven at trial against Gilead and in favor of the State of Rhode Island, plus a civil penalty of up to $10,000 for each violation of R.I. Gen. Laws § 9-1.1-3;

454. Judgment in an amount equal to threefold the damages to be proven at trial against Gilead and in favor of the State of Tennessee, plus a civil penalty of up to $10,000 for each violation of Tenn. Code Ann. § 71-5-182;

455. Judgment in an amount equal to threefold the damages to be proven at trial against Gilead and in favor of the State of Texas, plus a civil penalty of up to $10,000 for each violation of Tex. Hum. Res. Code Ann. § 36.002;

456. Judgment in an amount equal to threefold the damages to be proven at trial against Gilead and in favor of the State of Virginia, plus a civil penalty of up to $10,000 for each violation of Va. Code Ann. § 8.01-216.3;

457. Judgment in an amount equal to threefold the damages to be proven at trial against Gilead and in favor of the State of Utah, plus a civil penalty of up to $10,000 for each violation of Utah Code Ann. § 26-20-7;

458. Judgment in an amount equal to threefold the damages to be proven at trial against Gilead and in favor of the State of Wisconsin, plus a civil penalty of up to $10,000 for each violation of Wis. Code Ann. § 20.931(2);

459. Judgment in an amount equal to threefold the damages to be proven at trial against Gilead and in favor of the City of Chicago, plus a civil penalty of up to $10,000 for each violation of Chicago Municipal Code, tit. 1, ch. 1-21-010;

460. An award to the Relators of the maximum amount allowed pursuant to § 3730(d) of the FCA, and the equivalent provisions of the state statutes and municipal ordinances alleged above;

461. That the Relators, the Government and the States be awarded all reasonable attorney fees and costs incurred, including expert witness fees;

462. That the Relators, the Government and the States be awarded pre-judgment interest;

463. That the Relators, the Government and the States be awarded post-judgment interest;

464. That Relators be awarded all general damages, including but not limited to, pain and suffering;

465. That the Relators, the Government and the States be awarded all double, treble, exemplary, and/or punitive damages and penalties, including but not limited to, penalties under any and all of the false claim statutes set forth herein, the California Labor Code, and the Fair Labor and Standards Act;

466. That the Relators be awarded equitable relief, including but not limited to reinstatement and the payment of lost wages and benefits and liquidated damages, plus interest pursuant to California Labor Code § 98.6 and 29 U.S.C. § 216(b);

467. That the Relators be awarded all special damages, including, but not limited to, compensation for compensatory damages;

468. That Gilead cease and desist from violating 31 U.S.C. § 3729 et seq., and the counterpart provisions of the state statutes and city ordinances set forth above, and that the Relators be granted any and all preliminary and permanent injunctive relief, as appropriate;

469. That the Relators be granted any and all other relief set forth in the FCA and the counterpart provisions of the state statutes and city ordinances set forth above which was not specifically referenced above; and

470. That the Plaintiff-Relators be granted such other and further relief as the Court deems just and appropriate.

DATED: February 9, 2015.

BONNETT, FAIRBOURN, FRIEDMAN & BALINT, P.C.

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